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THE MEDICINE PARTNER

US MEDICAL

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For its Complaint in this matter, Plaintiffs, The Medicine Partners and G.C. Investments, hereby allege as follows:

NATURE OF THE ACTION

- 1. This action involves material misrepresentations and omissions made by a San Diego biomedical company, U.S. Medical Instruments, Inc., and its Chief Executive Officer, Matthew Mazur, in connection with the sale of the company's preferred stock. Plaintiffs purchased approximately \$8 million of U.S. Medical's Series E preferred stock after being informed repeatedly in U.S. Medical's written materials and orally by Mazur, that there already had been strong, existing sales of its first-ever product, a safety syringe, and that the company's financial condition was good.
- 2. After investing, Plaintiffs discovered that while
 Defendants were speaking of booming sales, they had yet to make any
 sales. The company's production was plagued with problems that
 had delayed manufacture of some syringe sizes and completely halted
 the manufacture of others. Because sales were contingent on U.S.
 Medical being able to deliver all four sizes (1cc, 3cc, 5cc, and
 10cc) -- a fact also left undisclosed by Defendants -- the company
 knew that it would be unable to achieve the sales it projected.
- 3. Plaintiffs have demanded return of their investment, but Defendants have refused. Currently, U.S. Medical survives on a week-to-week basis, satisfying cash and payroll needs by raising money from new investors. The financial disclosures to those new investors are, as yet, unknown to Plaintiffs.

PARTIES

4. Plaintiff The Medicine Partners is an Illinois general partnership formed in December 1994 for the purpose of investing in securities of U.S. Medical. Its partners are Illinois citizens and residents.

- 5. Plaintiff G.C. Investments is a limited-liability corporation organized and existing under the laws of the State of Nevada.
- 6. Defendant U.S. Medical is a technology-based medical device manufacturer. It is a California corporation headquartered in San Diego. Its first product was supposed to be the SafeSnap line of disposable safety syringes.
- 7. Defendant Mazur was U.S. Medical's chief executive officer and president. Mazur is a California citizen and resident and currently serves as a director of U.S. Medical.

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JURISDICTION AND VENUE

- 8. This court has jurisdiction over this action under 28 U.S.C. § 1332. The Medicine Partners is an Illinois general partnership with its principal place of business in Chicago, Illinois. Its partners are Illinois citizens and residents. G.C. Investments is a Nevada limited liability corporation with its principal place of business in Las Vegas, Nevada. U.S. Medical is incorporated in California and has its principal place of business in San Diego, California. Mazur is a citizen and resident of California. The amount in controversy, exclusive of interest and costs, exceeds \$50,000.
- 9. Venue is proper in this district under 28 U.S.C. § 1391(a) because a substantial part of the acts and omissions giving rise to this claim occurred here.

BACKGROUND

became aware of an idea for a new disposable safety syringe. The syringe features a needle that drops into the barrel of the syringe after use, thereby making it unnecessary to place a cap back on the needle. This reduces the chance of injury and infection attributable to accidental syringe wounds that might occur in the handling and disposal of used syringes. Convinced that he could generate substantial sales for the new product, Mazur formed U.S. Medical in June 1991, ultimately issuing to himself or members of his family a majority of the shares of common stock and Series A preferred stock.

- 11. Over the next three years, Mazur and U.S. Medical continued to work on developing what came to be known as the SafeSnap syringe. As part of this process, they raised \$11 million in "seed" capital through private placements of equity securities. By August 1994, U.S. Medical was actively looking not to raise more "seed" capital, but instead, to raise late-stage venture capital through the issuance of Series E preferred stock. Yet around this same time, U.S. Medical was encountering debilitating problems, particularly with its manufacturing.
- 12. Prototypes of the 5cc syringe were so riddled with leaks that the company's Vice-President of Quality and Regulatory Affairs Sally Grigorieu, had declared them unfit for human use and refused to permit their sale. And although 3cc syringes were being manufactured, they were available only in small quantities and were also of relatively poor quality.
- 13. At a meeting of U.S. Medical's sales and distribution personnel in August 1994, Carlos Manjarrez, U.S. Medical's Vice-President for Research and Development, announced that commencement of production on the 1cc and 10cc syringe would be delayed indefinitely because of manufacturing problems.
- 14. In light of Manjarrez's announcement, Ron Benincasa, who at that time was U.S. Medical's Senior Vice President of Marketing and Sales, and others involved in sales and marketing determined that the company's inability to have a full range of products this late in the fiscal year meant that U.S. Medical would never be able to generate sales sufficient to achieve the targeted revenues of \$7.5 million. Benincasa repeatedly told Mazur that the company would not reach its targets because "you can't sell, what you don't

have." He suggested that Mazur revise his projections to reflect reality.

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Inquiries By Plaintiffs

15. G.C. Investments was established by a number of individual investors. Brian Greenspun is and was the manager for G.C. Investments. In the summer of 1994, a friend told Greenspun about U.S. Medical and the market potential for its retractable syringe. Greenspun expressed interest in the potential investment and arranged for an August meeting in San Diego with Mazur and Benincasa.

16. At that meeting, Mazur provided a full description of U.S. Medical and its new safety syringe. Mazur stated repeatedly that U.S. Medical was selling large volumes of syringes and that even then, U.S. Medical was having problems keeping up with demand. Mazur reported that U.S. Medical had a large amount of agreements to purchase well into the future and that because of this stability, new investment would bear a low risk. One result of SafeSnap's success, according to Mazur, was that the company was almost at its breakeven point, i.e., that the company was manufacturing and selling so many syringes that the marginal cost of producing more would be outpaced by the resulting revenues. Mazur also informed Greenspun that new investment funds would go only towards the purchase of new automated production equipment (which had been ordered and was almost ready for use), sales and marketing efforts, and working capital. Finally, Mazur added that U.S. Medical was different from many investments in that it had no debt.

- 17. One of the partners in The Medicine Partners is
 Andrew G. Bluhm, who, in the summer of 1994, also heard about
 U.S. Medical. To learn more about the company and its product,
 Bluhm met with Mazur in San Diego on September 17, 1994.
- 18. At that meeting, Mazur described his own background as well as the background of U.S. Medical and, specifically, the idea for a new safety syringe. Mazur enthusiastically explained that U.S. Medical was selling all that it could produce and that the company had to be careful not to fall behind lest it lose accounts. He claimed also that despite the fact that the retractable needle required more raw materials and assembly than conventional needles, the company's manufacturing, sales, and other costs would be as low as that of a regular, non-safety syringe.
- 19. As he had done with Greenspun, Mazur sought to emphasize the low risk of the investment and advanced development of the company's sales efforts. Specifically, he stated that there already had been strong sales in the millions of dollars. Further, Mazur said that many other customers had agreed to purchase millions of dollars more of the product and that the company would soon cover its overhead costs upon earning between \$6 and \$8 million in sales revenues. Mazur omitted to mention that these sales commitments were predicated on U.S. Medical having a full range of syringe sizes a state of affairs that the company was still far from achieving. In fact, the company had yet to make any sales of SafeSnap.

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- Mazur sought to reassure Bluhm further by informing him that the company had received a \$25 million buyout offer two years earlier, and before that, had been offered \$10 million for its patent rights. Mazur pointed to this as evidence that there simply was "little risk" in investing in U.S. Medical.
- Mazur informed Bluhm that the company had ordered 21. automated assembly equipment that would enable U.S. Medical to substantially increase its production and, in turn, its sales. That equipment, according to Mazur, would be ready in two months.
- After the meeting, Bluhm returned to Chicago and reported his findings to other potential investors. They authorized him to investigate further the possibility of making a substantial investment. Soon afterward, one of Bluhm's colleagues (and later a partner in The Medicine Partners), William J. Abrams, traveled to San Diego to meet with Mazur about a possible purchase of Series E During that meeting, Mazur repeated to Abrams the same things he had earlier told Bluhm.
- It is believed that in connection with its efforts to raise new "investment" capital, U.S. Medical's board of directors authorized Mazur to use and distribute two documents to potential The first was a July 1994 Business Plan. The second investors. was a Private Placement Memorandum ("PPM") dated August 15, 1994. Both documents (collectively "Offering Materials") contain several materially fraudulent statements.

Offering Materials Are Sent To Plaintiffs
Making Representations About Production,
Existing Sales, Availability of a Full Product Line,
Arrival of Assembly Equipment, and Patent Costs

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24. At the August 1994 meeting, Mazur gave Greenspun a packet of U.S. Medical material which consisted of the Offering Materials. On September 22, 1994, Mazur sent to Bluhm the offering materials and sales brochures. He also sent information on patents and patent rights owned by U.S. Medical. When these documents were distributed to Plaintiffs, each contained material misrepresentations about a variety of topics including: production capacity, existing sales, the availability of a full product line, the expected date on which the new assembly equipment would arrive,

25. The Offering Materials, attached as Exhibits 1 and 2, specifically represented that U.S. Medical intended to "manage" its 1995 fiscal year production so as not to exceed 29 million units. (The company's 1995 fiscal year ran from February 1, 1994 to January 31, 1995.) Capping production (and thereby sales) at this level would allow the company to avoid the higher costs associated with outsourcing its production capacity. Implicit in these representations was that U.S. Medical was capable of producing at least 29 million units:

and the cost of the company's patent obligations.

While the Company's production capacity for the syringe parts has been increasing rapidly during fiscal 1995, Management will limit its production for the current year to 29 million units, in order to avoid the higher cost of sub-contracted assembly. The 29 million units in fiscal 1995 will permit the U.S. Medical marketing and sales force to target and sell to high-profile customers, secure high volume

purchasing contracts for the 1995 calendar year, and launch a successful marketing campaign for the SafeSnap product line.

Ex. 1 at 6. But in fact, because of U.S. Medical's numerous manufacturing problems, it could never have produced this many units in the remaining five months of the fiscal year.

U.S. Medical was aware of this when Mazur met with Bluhm and Greenspun.

26. The Offering Materials also made specific representations about strong existing sales and agreements to purchase more:

The Company expects to sell 29 million units of its SafeSnap syringes, achieving revenues of \$7 million, by fiscal year ended January 31, 1995, based upon the current assembly capacity of its subcontractors, Nypro Precision Assemblies and Kendall Healthcare, along with the soon-to-be implemented high-speed assembly automation. The Marketing and Sales department has already received either written or verbal purchase commitments for [a] large percent of those 29 million units, through its recently established Master Dealer Network of distributors.

Ex. 2 at 19. (Emphasis added.) Yet, as Plaintiffs discovered after making their investment, these agreements were contingent on the company having a full product line available. In fact, U.S. Medical did not begin shipping products (3cc syringes only) until November of 1994, and many of these initial shipments were for customers' test purposes and were not in fact sales.

U.S. Medical's first sale was not until November 21, 1994. By the

fiscal year's end, U.S. Medical's sales revenues totaled a mere

- 27 \$44,000 for approximately 200,000 units.

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27. The Offering Materials also provided examples of specific sales. For instance, the Business Plan stated that U.S. Medical had recently made a sale worth almost \$90,000 to Johns Hopkins Home Healthcare:

> Johns Hopkins Home Healthcare in Maryland recently placed an order for more than 180,000 3cc SafeSnap syringes at an initial price of \$0.49 per unit. this instance, SafeSnap replaced the B-D generic syringes which were being purchased for \$0.18 per The master distributors are beginning to unit. target hospitals, with much early success.

- But in fact, Johns Hopkins Home Healthcare never Ex. 1 at 5. placed the order described above; it had done nothing more than inquire into the product's availability. And hospitals were unwilling to place orders unless a full product line was available.
- 28. Related to the misrepresentations about sales were misrepresentations about the availability of a full range of syringe sizes. Throughout the Offering Materials, the company claimed that the 3cc and 5cc versions of the SafeSnap were available for sale and that the 1cc and 10cc sizes would be marketed by January 1995:

The 3cc and 5cc SafeSnap syringe sizes are currently available for sale. . . . Management anticipates that the 10cc and 1cc SafeSnap sizes will be prepared for the market during the third and fourth quarters of fiscal 1995.

Ex. 2 at 6; see also id. at 13 ("Sales of the Company's only commercial products, the SafeSnap 3cc and 5cc syringes, began in May of 1994.") Investors were not informed, however, that the start of production of the 1cc and 10cc already had been postponed

such that they would not be available for market in fiscal 1995. Nor were they informed that prototypes of the 5cc syringe were leaking so badly that company had determined that it was not fit for human use and that quantities of the 3cc syringe were limited. Indeed, as Benincasa anticipated in August 1994, the unavailability of three of four sizes was the main reason U.S. Medical fell so woefully short of its projections.

Also repeated throughout the Offering Materials is that the new automated assembly machinery, that would allow U.S. Medical to increase its production and shed the costs associated with its existing labor-intensive assembly system, would be ready in the final quarter of fiscal 1995:

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Management anticipates profitability on a monthly basis to begin in the last quarter of fiscal 1995, when the Company's automated assembly and packaging machines will be ready to replace the labor intensive sub-assembly performed at Kendall International.

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Ex. 2 at 13. But Plaintiffs learned after making their investment that nobody at U.S. Medical had ever expected the machinery to be delivered until the middle of fiscal 1996 at the earliest. Indeed, it was not scheduled to be delivered any earlier. Yet, projections as to the company's performance in 1996 were premised on the equipment being operative for the entire year. Consequently, these projections were false when made.

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30. With respect to patents and patented technology, U.S. Medical represented in the Business Plan that it already owned all of the intellectual property necessary to produce the safety syringe. With respect to "Patent Coverage" the plan simply stated:

U.S. Medical owns the exclusive right to make, use and sell the proprietary property of patents pending covering the SafeSnap design and all designs associated with the development of this product. The first two patents of the several filed were assigned U.S. No. 5,205,824 and 5,308,329, and were issued in April 1993 and May, 1994, respectively. U.S. Medical's patent position is further strengthened with the exclusive license of a key patent from Habley Medical Technology, Inc. The combination of these three patents, in addition to the patents still pending, represent a significant competitive barrier in the retractable safety syringe industry.

Ex. 1 at 5. Nowhere, however, did the Business Plan disclose that there was a substantial patent royalty that was tied to sales.

Further Representations By Mazur to G.C. Investments and First Purchase

31. In or around September 1994, at Greenspun's request, Phil Peckman met with Mazur to discuss and investigate further the possibility of a potential investment in U.S. Medical. Peckman is the chief operating officer for the entity that provides management services to G.C. Investments. At this meeting, Mazur told Peckman that U.S. Medical was not able to fully meet the market demand for the syringes, and that U.S. Medical was selling all of the syringes that it could produce. He also assured Peckman that any funds invested by G. C. Investments would go towards the new automated

equipment, increased marketing efforts, and working capital.

Again, he stated that U.S. Medical had no debt.

- 32. Around the same time, Greenspun and William Weinberger, an investor in G.C. Investments, met with Mazur to discuss and investigate the potential for an investment in U.S. Medical. At this meeting, Mazur repeated the representations he had made in his meeting with Peckman and added that customers already had agreed to buy 30% of the syringes to be produced for the next three years. Mazur also claimed that U.S. Medical would reach \$7 million in net profits for the next fiscal year, and that it would be a \$100 million company in a short time.
- 33. On or about October 4, 1994, G.C. Investments purchased approximately \$1.875 million worth of U.S. Medical Series E preferred stock.

Further Representations By Mazur to The Medicine Partners and Purchase

34. On October 13, 1994, Bluhm and Abrams again traveled to San Diego to meet with Mazur at U.S. Medical in order to discuss a possible investment in the Series E preferred stock. Much of the discussion was devoted to production costs, breakeven analysis, and sales. Mazur repeatedly characterized sales as "strong" and assured Bluhm and Abrams that the company would have "no problem" meeting sales projections. Indeed, he specifically stated again that the company was just about at the breakeven point. He also announced that the new automated assembly equipment was ready.

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- 35. With respect to production costs, Mazur stated that the main costs were material, overhead and assembly. At no time did he mention that there was a patent royalty, let alone that the royalty was as high as six percent of sales.
- 36. On October 21, 1994, Mazur wrote Bluhm a memorandum (attached as Exhibit 3) regarding the September 1994 financial statements for U.S. Medical and 2,000,000 "shipments." In it, Mazur painted a falsely optimistic picture of sales and the future of the company:

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The Company has shipped approximately 2,000,000 syringes year to date. Early in the first quarter the Company made a decision to wait until discounts associated with large volumes allow the Company to make gross margins in excess of 50%. This entailed high cavity molds coming on line to produce volumes in excess of 3 million units a month. The Board believed shipping every syringe at a loss for the last six months would have spent too much of the Company's working capital. The Board was right. In August the Company realized a \$0.063 per unit discount from what it had previously been paying for the same assembly labor charges in Mexico. The Company is on pace to produce and sell 15 million units for the fourth quarter and is within 30-60 days of next year's budget.

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37. As it turns out, however, these shipments were never made. U.S. Medical's first shipments were not until November of 1994. In fact, the company did not start producing 3cc syringes of marketable quantity and quality until October 28, 1994, seven days after this memorandum was written.

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memorandum also painted a healthy picture for U.S. Medical. Among other things, the financial statements represented that U.S. Medical was in a very liquid financial position, having approximately \$2.2 million in current assets compared to only \$1.6 million in current and long-term liabilities. These financial statements did not disclose the existence of any demand notes held by management, including those held by Mazur. The same memorandum and statements were sent to G.C. Investments and relied upon in its second purchase.

Mazur Meets With The Medicine Partners in Chicago

- 39. On October 28, 1994, Mazur met with individual members of The Medicine Partners in Chicago. After giving these partners a general overview of the business and expected profits, Mazur made some specific representations. First, he stated that U.S. Medical already had sold one million syringes in October 1994 and expected to sell 2.6 million units and 4 million units in November and December, respectively. Second, he represented that in October 1994, U.S. Medical earned sales revenues of \$250,000 and expected to earn \$650,000 and up to \$1.2 million in November and December, respectively. There was no cautionary language accompanying these forecasts; he led the investors to believe that these projections were based on existing sales rates. In fact, Mazur claimed that there was a sales backlog of 42 million units.
- 40. At the Chicago meeting, Mazur reported that the new syringe assembly machine was being "debugged," and would be delivered in November.

Representations Regarding Sales In November And December 1994

- 41. Mazur's campaign to raise money from The Medicine
 Partners continued into November and December, and as part of his
 efforts, he continued to boast of strong sales. Additionally, in a
 series of phone conversations with Bluhm, Mazur stated that the
 company was on pace to sell 2.6 million syringes in November and
 projected that it would sell another 4.5 million in December and up
 to 10 million in January 1995. He claimed also that the full
 product line was nearly ready.
- 42. Later, as the parties began negotiating the terms of a purchase and other agreements relating to the Series E preferred stock, Mazur continued to reassure The Medicine Partners of existing sales. He specifically told Bluhm that there had been large sales to Taylor Medical, Life Systems, and St. Barnabus Hospital. Mazur also tried to pressure The Medicine Partners' investment by repeatedly telling Bluhm that there was an imminent board-instituted deadline for Series E purchases. Nevertheless, no mention of such deadlines appear in the board minutes around this time.
- 43. On November 21, 1994, U.S. Medical made its first sale of syringes. That this was its first sale was of course unknown to Plaintiffs.
- 44. In or around early December 1994, U.S. Medical conducted a board of directors meeting by telephone. Greenspun, pursuant to the October 4, 1994 investment by G.C. Investments, had been appointed to the board and participated in the meeting. During the meeting, the board approved a resolution by which investors in U.S.

Medical with investments of \$4 million or more would receive, as a bonus, certain extra rights in the form of stock warrants.

45. Mazur was not finished with G.C. Investments. He continued to campaign for additional money from Greenspun, and as part of his efforts, he continued to make representations regarding strong and growing sales of the safety syringe. In or around December 1994, Mazur met with Greenspun to discuss an additional investment by G.C. Investments in U.S. Medical. Mazur stated that although U.S. Medical was not in need of any additional funds, another investment by G.C. Investments would be a "great deal" because it could then qualify for the bonus warrants. Mazur promised that any additional investment would be placed in U.S. Medical's bank account to be used for working capital when needed.

The Medicine Partners Purchases \$4 Million Of Series E Preferred Stock

- 46. As negotiations with The Medicine Partners neared completion, U.S. Medical gave The Medicine Partners until January 15, 1995 to purchase the Series E stock. Nevertheless, well before the deadline, Mazur called Bluhm and strongly encouraged him to make the investment sooner so that the funds could be put toward working capital expansion as soon as possible. He claimed that others had already invested in the Series E offering. Finally, on December 19, 1994, The Medicine Partners purchased \$4 million worth of Series E preferred stock.
- 47. The parties agreed that disputes arising from the stock purchase would be governed by the law of California.

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G.C. Investments Purchases Additional \$2.125 Million of Series E Preferred Stock

- 48. On or about January 31, 1995, G.C. Investments purchased additional U.S. Medical Series E preferred stock worth approximately \$2.125 million, bringing its stake in U.S. Medical to \$4 million.
- 49. As was true of their earlier transaction, the parties agreed that disputes arising from the stock purchase would be governed by the law of California.

The Deteriorated Financial Condition Of The Company Is Revealed To Plaintiffs

- 50. Bluhm, now The Medicine Partners' board representative, attended his first U.S. Medical board meeting in late

 February 1995. Greenspun, as the G.C. Investments representative was also in attendance. Upon reviewing materials for the meeting, both men learned for the first time that several of the oral and written statements that had been made to them and upon which Plaintiffs had relied in determining the risk profile of U.S.

 Medical, the price of the Series E stock, and in deciding whether to invest, were all false. For example, they discovered:
 - There had been virtually no sales of any product at any time;
 - Projected sales forecasts were baseless;
 - The company still was nowhere close to having a full line of syringes;

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- The company owed a sizable number of debts, including some to Mazur;
- There was a substantial royalty that had to be paid on a critical patent; and
- Far from being at the "debugging" stage as represented by defendants, the new automated assembly machinery that was absolutely critical to achieving significant efficiencies was not even scheduled to be delivered in the foreseeable future.
- 51. Benincasa told Plaintiffs for the first time that the company was not yet producing the 1cc and 10cc syringes and that the 3cc syringes had not even been produced in marketable quantities until October. Before that, production had been of limited quantity and poor quality and simply was not marketable.
- Benincasa contradicted Defendants' accounts of purported For instance, the company had never sold syringes to Johns Hopkins Home Healthcare, and the alleged St. Barnabus transaction had collapsed when U.S. Medical had been unable to provide a full product line.
- Plaintiffs learned from Scott Dolin, U.S. Medical's Director of Operations, that the assembly equipment was not even due to be delivered for another 4-6 months.
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- 55. Other board members expressed surprise and concern that Bluhm and Greenspun had been so misinformed. Bluhm confronted Mazur after the board meeting and demanded his investment be returned. Upon being rebuffed in his request, Bluhm resigned his board position. Greenspun also subsequently resigned from the board. Thereafter, defendants continued to refuse plaintiffs' repeated requests to return the investment money.
- 56. Plaintiffs later learned that as early as January 1995, U.S. Medical was experiencing near-weekly or bi-weekly cash crises. U.S. Medical and, specifically, Mazur, with the board's approval, was continually raising monies through various forms of debt or other investment just to keep the company solvent. Some of the money raised was additional Series E money.
- 57. Plaintiffs also discovered that rather than going toward working capital, equipment and expansion, as represented in the written offering materials and by Mazur, most, if not all of Plaintiffs' investment had been diverted to pay existing creditors. Indeed, some of the money was used to pay off a demand note that Mazur had received from U.S. Medical in 1994 in exchange for a loan to help the company meet its payroll.

- 58. As late as March 31, 1995, U.S. Medical was still not producing a full range of syringes.
- 59. In October 1995, plaintiffs obtained a copy of U.S.

 Medical's audited financial reports for the fiscal year ending

 January 31, 1995 (attached as Exhibit 4). These documents

 confirmed plaintiffs' worst fears: U.S. Medical had recorded sales

 worth \$44,000, which translated into approximately 200,000 units

 sold—a far cry from the 1 million and 2.6 million syringes that

 Mazur claimed had been sold in October and November of 1994

 respectively, not to mention the 29 million units projected in the

 Offering Materials.
- in San Diego to discuss U.S. Medical. Specifically, Greenspun confronted Mazur about the representations Mazur made to Plaintiffs prior to their investment; namely, that U.S. Medical had no debt, that U.S. Medical was selling all of the syringes that it could make and could not keep up with demand, and that Plaintiffs' investment money would be used for new production equipment, increased marketing efforts, and working capital. Greenspun stated to Mazur that these and other representations were not true. Mazur acknowledged that Greenspun was right, and admitted that he, Mazur, "had gone too far."

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61. On February 16, 1996, Mazur entered into an agreement with The Medicine Partners in which Mazur and U.S. Medical agreed not to raise a statute of limitations or "other potential time bar" response to an action brought by The Medicine Partners before June 30, 1996. Mazur and U.S. Medical entered into a similar agreement with G.C. Investments. (Both agreements are attached as Exhibit 5.)

Count I Violation of Section 25401 Of The California Corporations Code

62. Paragraphs 1 through 61 are incorporated herein by reference.

63. Section 25401 of the California Corporations Code provides liability for untrue statements or omissions in connection with an offer to sell a security:

It is unlawful for any person to offer or sell a security in this state or buy or offer to buy a security in this state by means of any written or oral communication which includes an untrue statement of a material fact or omits to state a material fact necessary in order to make the statements made, in the light of the circumstances under which they were made, not misleading.

64. Section 25501 of the California Corporations Code provides remedies to a plaintiff who can establish liability under \$ 25401:

 Any person who violates Section 25401 shall be liable to the person who purchases a security from him or sells a security to him, who may sue either for rescission or for damages (if the plaintiff or the defendant, as the case may

be, no longer owns the security), unless the defendant proves that the plaintiff knew the facts concerning the untruth or omission or that the defendant exercised reasonable care and did not know (or if he had exercised reasonable care would not have known) of the untruth or omission. Upon rescission, a purchaser may recover the consideration paid for the security, plus interest at the legal rate, less the amount of any income received on the security, upon tender of the security.

- 65. The Series E preferred stock purchased by Plaintiffs was a security within the definition of Section 25401.
- 66. In connection with the sale and purchase of the Series E stock, Mazur and U.S. Medical made numerous written and oral representations to plaintiff. Several of these representations included both untrue statements of material fact as well as omissions of material facts necessary to make the statements made, in the light of the circumstances which they were made, not misleading.
- 67. Defendants made numerous written and oral statements to Plaintiffs that were flatly inconsistent with the facts as known to Defendants, including, but not limited to, the following:

•Production: U.S. Medical stated in its Offering
Materials distributed in August and September of 1994,
that although demand was higher, it was capping its
production at 29 million units so as not to outsource its
production. Then again, on October 21, 1994, Mazur told
both Bluhm and Greenspun that U.S. Medical had already
shipped 2 million units and was on pace to produce an

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additional 15 million units. These statements were false when made. As Bluhm and Greenspun learned from Benincasa, management was aware as early as August 1994, that with all the problems they were having, U.S. Medical would never be able to produce anywhere close to this many units. Moreover, the company did not start producing 3cc syringes of marketable quality and quantity until October 28, 1994, a week after Mazur's representation. Yet Defendants never revised their baseless statements.

• Existing Sales: In his initial discussions with Plaintiffs, Mazur spoke of existing sales worth millions of The Offering Materials falsely reported a significant sale to Johns Hopkins Home Healthcare and stated that the company was succeeding in its efforts to sell syringes to hospitals. In communications leading up to Plaintiff's investments, Mazur reported that U.S. Medical had sold 1 million syringes in October alone and was on pace to produce and sell 15 million syringes by year-end, and on more than one occasion, he characterized sales as strong enough that the company would cover its overhead costs. As pointed out above, none of this was ever true; U.S. Medical made its first sale in late November 1994 and sold only around 200,000 syringes in the entire fiscal year 1995. Johns Hopkins made no purchases and hospitals were not buying SafeSnap products because a full product line was not yet available. Defendants never had a reasonable basis for making these claims.

•Existing Customers: The Business Plan claimed that several hospitals and care facilities had already agreed to purchase SafeSnap syringes. Mazur compounded the fraud later in the fall when he identified several accounts that had purportedly placed significant orders. Each of these representations was false. As of March 1995, only one hospital had elected to carry SafeSnap syringes. Other alleged "purchasers" had done no more than express interest and even then were only interested if U.S. Medical could furnish a full range of sizes.

•New Assembly Equipment: In his first meetings with Plaintiffs, Mazur stated that the new assembly equipment that was critical to increasing efficiency and output would be ready in the fall of 1995. The Offering Materials confirmed this falsehood, stating that the machinery was to be ready and operating by the end of fiscal 1995. In his Chicago presentation in October 1994, Mazur stated it was to be delivered in November. These statements were false when made. In fact, the equipment was not even scheduled to be delivered until mid-to-late fiscal 1996. This misrepresentation was material because Plaintiffs' assessment of the company's value was based on its projected performance in the upcoming years. Projections for 1996 were based on U.S. Medical having the new equipment up and running for the entire fiscal 1996 year.

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68. Defendants also repeatedly omitted material information from their statements rendering their statements false or at least misleading, including, but not limited to, the following:

•Availability of a full product line: The Offering

Materials represented that the 3cc and 5cc SafeSnap syringes

were already being sold and that the 1cc and 10cc versions

would be available by the end of fiscal 1995. Not only was

this representation false but omitted relevant to reveal that

having all four sizes was critical to sales and that it was in

fact impeding the company's ability to sell to hospitals.

They then compounded that misrepresentation by failing to

disclose that the 3cc syringe was not available until

October 1994 and that as a result of production problems, the

1cc, 5cc, and 10cc syringes would be nowhere near ready for

sale by January 1995.

•Patent royalty: In speaking about patent coverage, neither the Offering Materials nor Mazur disclosed the true cost of the royalty payment. In fact, the license on one of the key patents was obtained on the condition that the company pay a royalty to the licensor that was as high as 6 percent of the company's sales.

•Short-term debt: Mazur failed to disclose the full extent of U.S. Medical's short-term debt obligations including obligations held by Mazur himself. Mazur repeatedly represented to Plaintiffs that U.S. Medical had no debt, and that any investment capital would be used only for automated production equipment, increased marketing efforts and working capital. Instead, the proceeds were used to pay off several undisclosed debts, including, upon information and belief, some owed to Mazur. Use of the funds for these debts went beyond "general corporate purposes."

- 69. Defendants' written and oral misrepresentations were not made contingent on any conditions nor were they accompanied with statements of caution.
- 70. Plaintiffs did not discover the truth until late February 1995 when Greenspun and Bluhm were provided with the true and actual information concerning the status of U.S. Medical.
- 71. Plaintiffs relied upon the misleading statements referenced in the preceding paragraphs and have suffered damage as alleged in greater detail below.
- 72. Defendants' misrepresentations were willful, malicious, and in reckless disregard of plaintiff's rights and entitle Plaintiffs to an award of exemplary damages in an amount to be determined.

Count II Joint and Several Liability as Control Person Under § 25504 of the California Corporations Code

73. Paragraphs 1 through 72 are incorporated herein by reference.

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74. Section 25504 of the California Corporations Code provides for joint and several liability of any person who controls a person directly liable under section 25501.

75. At all relevant times, Mazur was a person who "directly or indirectly controlled" U.S. Medical within the meaning of Section 25504 because Mazur was the principal executive officer and was involved in the day-to-day business operations of U.S. Medical. Further, Mazur also had control of the board of directors. Mazur therefore is jointly and severally liable for the damages suffered by Plaintiffs as a result of the primary violations of Section 25401 by U.S. Medical.

Count III Fraud and Deceit

- 76. Paragraphs 1 through 75 are incorporated herein by reference.
- 77. Defendants' representations, as alleged in detail above, were flatly inconsistent with the facts as known to Defendants. As such, those representations were both misleading and false. The failure to disclose the production flaws that had delayed indefinitely production of three of four syringe sizes as well as the significant patent royalty payments rendered the statements misleading. Affirmative representations about production, sales, and the assembly equipment were simply false.
- 78. When they made these misrepresentations, Defendants knew that they were misleading and/or false.
- 79. By making these misrepresentations, Defendants intended to deceive Plaintiffs; specifically, Defendants intended for

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Plaintiffs to rely on the statements in making a decision on whether to invest.

- Plaintiffs did in fact rely on these misrepresentations 80. in investing in the Series E offering.
- Plaintiffs were justified in their reliance on the misrepresentations because the statements were not accompanied by any cautious language nor were they made contingent on certain conditions. They were made as statements of fact.
- As a result of their reliance on the misleading statements referenced above, Plaintiffs invested in a significantly riskier venture than it believed and suffered damage as alleged in greater detail below.
- Defendants' misrepresentations were willful, malicious, and in reckless disregard of plaintiff's rights and entitle Plaintiffs to an award of exemplary damages in an amount to be determined.

Count IV Negligent Misrepresentation

- Paragraphs 1 through 83 are incorporated herein by reference.
- Defendants' promotional representations, as alleged in detail above, were material to Plaintiffs' evaluation of the Series E offering. They were, however, both misleading and false.
- Defendants were negligent in making these misrepresentations and/or omissions. When these statements were made, Defendants were aware of facts that made the representations /////

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Since June 30, 1994, except as contemplated by

this Agreement, there has not been:

- (a) any change in the assets, liabilities, prospects, financial condition or operations of the Company from that reflected in the Financial Statements, except changes in the ordinary course of business which have not been, either in any case or in the aggregate, materially adverse;
- (b) any material increase in the outstanding indebtedness owed by the Company

Id. at 3-4

- 93. In making this warranty, the company failed to reveal that its manufacturing had been so fraught with problems and delay, that as early as August, management was urging that Mazur revise its projections so that 1995's targets be carried over to 1996, 1996's targets be carried over to 1997, and so on.
- 94. Plaintiffs have performed all of their obligations under the Agreement including payment for the stock.
- 95. As a result of U.S. Medical's breach of the Agreement, Plaintiffs have incurred damage alleged in greater detail below.
- 96. The Agreement contains a choice-of-law clause designating the law of California as the law governing the agreement. (§ 9.1).

Count VI Breach of Fiduciary Duty Against Mazur

- 97. Paragraphs 1 through 95 are incorporated herein by reference.
- 98. By virtue of Mazur's position as a controlling shareholder of U.S. Medical, and by virtue of his position on, and the ability to control, the board of directors of U.S. Medical, Mazur owed a fiduciary duty to Plaintiffs as shareholders of U.S. Medical.

Mazur engaged in the aforesaid conduct without exercising the reasonable, ordinary or fiduciary care owed to plaintiffs as shareholders of U.S. Medical.

100. As a result of these breaches of fiduciary duty by Mazur, plaintiffs have suffered damages in an amount to be proven at trial.

101. Mazur's breaches of fiduciary duty were willful, malicious, and in reckless disregard of Plaintiffs' rights and entitle Plaintiffs to an award of exemplary damages in an amount to be determined.

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PRAYER FOR RELIEF

WHEREFORE, Plaintiffs demand the following relief:

- (1) Rescission of the stock purchase and return of plaintiff's consideration plus interest at the legal rate pursuant to California Corporations Code Section 25501. In the alternative, and in the event Plaintiffs sell such stock before judgment is entered, Plaintiffs seek damages equal to the difference in value between the purchase price and the price of sale plus interest at the legal rate pursuant to the aforementioned Sections 25501.
- (2) Compensatory damages for their actual fraud and/or deceit, breaches of contract, negligent misrepresentation, and breaches of fiduciary duty.
- (3) Punitive damages for their actual fraud and/or deceit, and breaches of fiduciary duty.
 - (4) Costs of suit.
 - (5) Such other relief as the Court deems just and proper.

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1 JURY DEMAND Plaintiffs hereby demand a trial by jury of the issues and 2 3 allegations raised by this Complaint. Dated: October **26**, 1996 4 LORENZ ALHADEFF CANNON & ROSE, LLP 5 6 Robert D. Rose 7 Frank J. Polek Attorneys for Walton Street Capital and 8 The Medicine Partners 9 Dated: October 21, 1996 KIRKLAND & ELLIS 10 11 12 13 Ram Padmanabhan Attorneys for Walton Street Capital and 14 The Medicine Partners 15 Dated: October 26, 1996 16 Leboeuf, LAMB, GREENE & MacRAE, L.L.P. 17 18 Vincent J. Davitt 19 Attorneys for Brian Greenspun and 20 G. C. Investments 21 22 23 24 25 26 27 28

U.S. Medical Instruments, Inc.

16825 Via Del Campo Court Rancho Bernardo, California 92127 (619) 674-7200

July 1994

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I. Executive Summary

I. Executive Summary

U.S. Medical Instruments, Inc., ("U.S. Medical" or the "Company"), is a technologybased medical device manufacturer with the mission of developing, manufacturing, and marketing safety-enhanced medical instruments that are both cost-effective and user-friendly. The California corporation's first product is SafeSnap™, a patented line of single-use hypodermic syringes that will substantially reduce the incidence of accidental needle sticks in the healthcare and homecare markets. The technically and aesthetically superior high-precision SafeSnap design is unlike any other syringe available on the market, in that it permits the used needle to retract into the syringe barrel, completely shielding the needle from human contact. Management intends to capture at least five percent of the more than 5 billion unit annual U.S. syringe market over the next five years, and use the resulting income and manufacturing capabilities as a platform for launching other safety-enhanced medical devices. Follow-on products include safety winged-butterfly catheters, vial adapters, safety arteriovenous fistula needles, and blood-gas syringes, currently in their early stages of development. Revenue from the core SafeSnap business alone is projected to reach \$42 million by the year ended January 31, 1997, with gross margins of approximately 50%.

MARKET OVERVIEW

The disposable hypodermic syringe represents the single largest segment of medical instrumentation in terms of units used, with more than 16 billion sold world wide annually, 4.6 billion in the U.S. alone in 1993. Due to universal concern over infectious diseases transmitted by reusable needles and syringes, worldwide syringe growth has been approximately 15% over the past few years and is expected to continue at that pace, as expressed in Becton Dickinson's 1991 Shareholders' Annual Report.

The Center for Disease Control reports that 12,000 needle stick injuries are reported in the healthcare environment each year, exposing workers to blood borne diseases such as Hepatitis B and AIDS. Reported deaths from contraction of Hepatitis B through needle sticks exceed 250 annually, while the number of total sticks leading to death by AIDS exceeds 36. Recent proposed legislation states that the cost of testing and counseling for each stick is \$600; this figure excludes the costs involved with treatment if an infection is detected. Expensive and reputation-damaging lawsuits by victims of sticks, along with mounting pressure from regulators and lawmakers (e.g. excise tax proposed for non-safety syringes) is driving healthcare organizations to examine safety syringe alternatives.

Independent industry studies estimated that safety syringes currently represent approximately 15% of the domestic syringe market, and may represent as much as 80% of the market within the next 5 years. (Theta Corporation, January 1994 Report #346 Medical Needles & Syringes). In a recent survey by Medical Product Sales as reported in their June 1993 issue "nearly half of the [surveyed 306 U.S. Hospitals] respondents said their facilities had purchased safety needles during the past year, and 14% said they planned to do so by mid-summer." Furthermore, their customer purchasing pattern survey concluded that 59% of those surveyed increased their purchases of safety needles over the past year (see Appendix). U.S. Medical intends to capture more than 5% of the domestic syringe market by fiscal 1997, representing annual revenues exceeding \$42 million, with its SafeSnap syringe line.

THE PRODUCT

The SafeShap design permits the used needle to retract into the barrel of the syringe, shielding it from human contact and preventing re-use - thereby providing a level of safety never before available in generic or safety syringes. Since the distinction in design is internal, SafeSnap requires limited technique change and appears aesthetically similar to non-protective syringes.

Besides U.S. Medical, Becton Dickinson and Sherwood Medical are the two principal companies selling safety syringes. Safety syringes have already established premium pricing of three to five times that of generic syringes. While SafeSnap is superior in design to other safety syringes, it has the distinguishable cost benefit of a generic syringe's manufacturing cost with a premium sales price. Furthermore, in market evaluations conducted by several California healthcare organizations, nurses have expressed an overwhelming preference for SafeSnap over the safety syringes sold by B-D and Sherwood.

PATENT COVERAGE

٠:

U.S. Medical owns the exclusive right to make, use and sell the proprietary property of patents pending covering the SafeSnap design and all designs associated with the development of this product. The first two patents of the several filed were assigned U.S. No. 5,205,824 and 5,308,329, and were issued in April, 1993 and May, 1994, respectively. U.S. Medical's patent position is further strengthened with the exclusive licensing of a key patent from Habley Medical Technology, Inc. The combination of these three patents, in addition to the patents still pending, represent a significant competitive barrier in the retractable safety syringe industry.

SALES & MARKETING

The syringe market can be divided into three segments: hospitals; alternate care; and physician offices. Management has selected to penetrate these segments with the aid of distributor alliances and independent sales organizations. The primary market penetration strategy employed is to provide enough SafeSnap for organizations to conduct their own independent evaluations, while providing a thorough in-service program to the users. Many evaluations have been completed in Southern California, most of which have led to the demand for hospital and clinic conversions.

The 3cc and 5cc SafeSnap syringe sizes are currently available for sale. These two sizes account for approximately 60 percent of this market. U.S. Medical's recent boost in production capacity will permit the Company and its distributors to launch marketing and sales campaigns with the confidence that it can supply the anticipated demand. Management anticipates that the 10cc and 1cc SafeSnap sizes will be prepared for market during the third and fourth quarters of fiscal 1995.

USMI has recently formed alliances with 13 medical device master distributors, whose combined territories cover more than 40 of the American states. These master distributors are initially targeting the alternate care markets, including home healthcare, in order to take advantage of the premium pricing that those markets pay. For example, Johns Hopkins Home Healthcare in Maryland recently placed an order for more than 180,000 3cc SafeSnap syringes at an initial price of \$0.49 per unit. In this instance, SafeSnap replaced the B-D generic syringes which were being purchased for \$0.18 per unit. The master distributors are also beginning to target hospitals, with much early success.

USMI recently attended the Intravenous Nurses Society's National Convention ("INS") in Denver, as well as the American Association of Critical Care Nurses' National Convention ("NTI/CCN") in Atlanta and the Association of Practitioners of Infection Control ("APIC") in Cincinatti. At all three of these shows, SafeSnap received significant praise and attention, generating more than 500 solid leads for samples and requests for sales visits.

Several additional marketing opportunities are currently under discussion with recognizable healthcare concerns and international organizations, including distribution agreements, prepackaging of SafeSnap with other products in kits, OEM supplying & private labeling, prefilling, and international licensing agreements.

PRODUCTION

U.S. Medical is registered with the U.S. FDA as a medical device manufacturer. The company is vertically integrated with design, mold-making, manufacturing, assembly and packaging all in the same facility. Additional assembly and packaging is being performed at Kendall International's (an \$800 million revenue NASDAQ-traded healthcare company) Maquiladora facility. U.S. Medical recently moved to a 52,000 square foot facility in Rancho Bernardo, California, leased from McDonnell Douglas, which is extremely well-suited for its expansion of production capacity.

U.S. Medical has completed the various regulatory approval processes for the Rancho Bernardo facility, and the manufacturing process has since begun. All assembly operations are currently being conducted at the Kendall International Maquiladora facility. The first set of 3cc multicavity production tools, as well as seven new injection molding presses were received at the end of February, and permit U.S. Medical to meet its production forecasts for fiscal 1995. These molds have the production capacity of at least 5 million units per month.

Management anticipates profitability on a monthly basis to begin in the last quarter of fiscal 1995, when the Company's automated assembly and packaging machines will be ready to replace the labor intensive sub-assembly performed at Kendall International. While the Company's production capacity for the syringe parts has been increasing rapidly during fiscal 1995, Management will limit its production for the current year to 29 million units, in order to avoid the higher costs of sub-contracted assembly. The 29 million units in fiscal 1995 will permit the U.S. Medical marketing and sales force to target and sell to high-profile customers, secure high volume purchasing contracts for the 1995 calendar year, and launch a successful marketing campaign for the SafeSnap product line.

The Company anticipates that additional sets of high-cavitational molds and high speed assembly and packaging automation will come on-line throughout fiscal 1996 and 1997 such that total production capacity will be 144 million units and 300 million units, respectively, with revenues for the year of \$25.9 million and \$42 million, respectively. Furthermore, Management anticipates that it will first achieve profitability as soon as the first quarter of fiscal 1996.

NEW PRODUCTS

The full line of SafeSnap syringes will be the anchor product line to US Medical's additional safety-enhanced devices as well as some traditional devices. These products include stickless winged-butterfly catheters, vial adapters, safety arteriovenous fistula needles, and blood-gas syringes. Revenues and profits from these encore products is not included in the current business plan or its pro forma financials.

MANAGEMENT

U.S. Medical's management team brings together a talented group of seasoned, highly-qualified executives and engineers, many of whom have worked for Becton Dickinson, Sherwood Medical or other successful healthcare concerns.

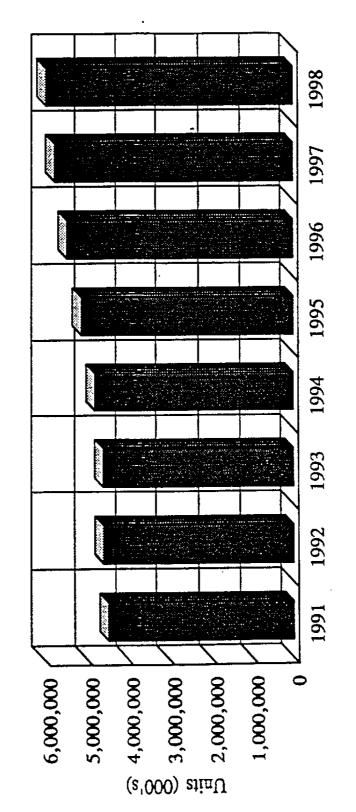
CAPITAL

The company has independently raised more than \$10 million of seed capital since incorporation in June, 1991. Investment capital is presently being sought in the amount of \$7.5 million. The new capital would be applied toward the purchase of additional sets of molds, additional injection molding machines, assembly and packaging automation equipment and working capital required to meet the business plan.

II. Market Overview

Total Syringe & Needle Market

UNIT SALES PROJECTIONS

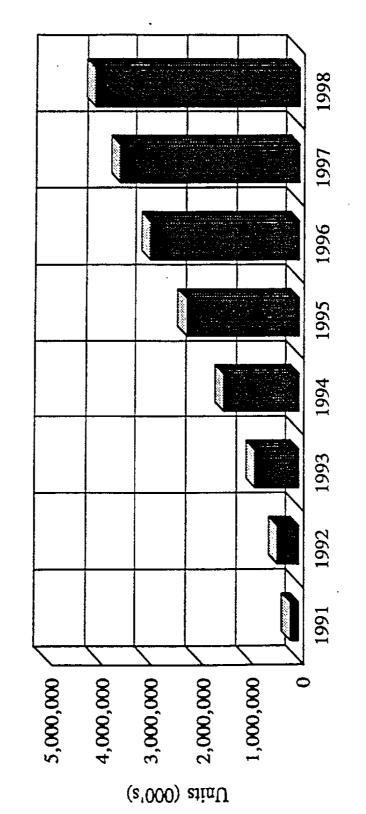


SOURCE: THETA CORPORATION, 1994

Total Safety Syringe & Needle Market

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UNIT SALES PROJECTIONS

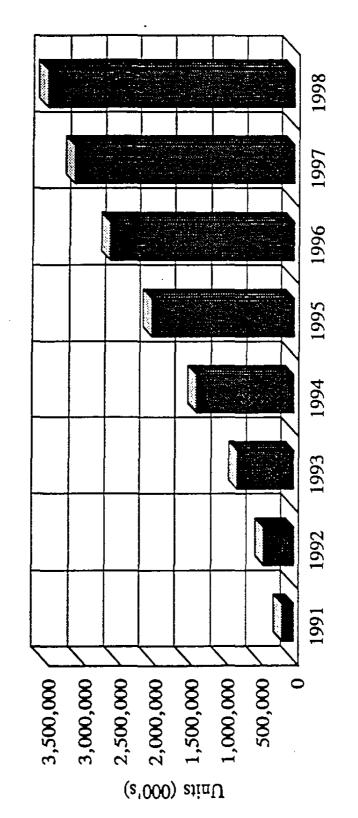


SOURCE: THETA CORPORATION, 1994

EXHIBIT 1

Hypodermic Safety Syringe Market

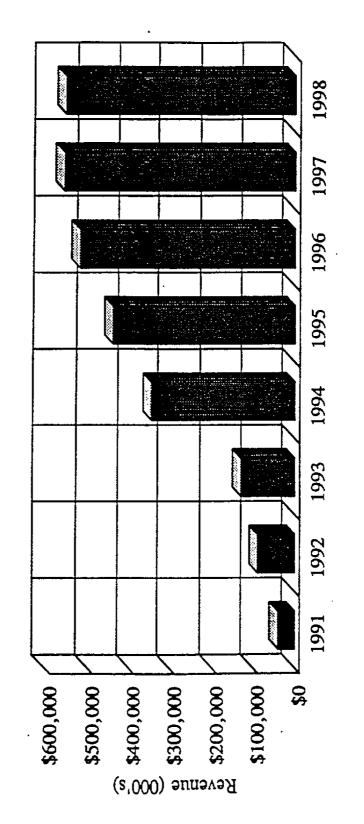
UNIT SALES PROJECTIONS



SOURCE: THETA CORPORATION, 1994

Hypodermic Safety Syringe Market

REVENUE PROJECTIONS



SOURCE: THETA CORPORATION, 1994

Selected Niche Markets

ACUTE CARE

- Emergency
- PACU (Post Anesthesia Care Unit)
- **Pediatrics**
- Psychiatrics •
- Rheumatology

Selected Niche Markets

ALTERNATE CARE

• Dialysis

• Home health

• Immunization clinics

• Long term care

Outpatient care/ambulatory surgery

WS MEDICAL

Safety Syringe

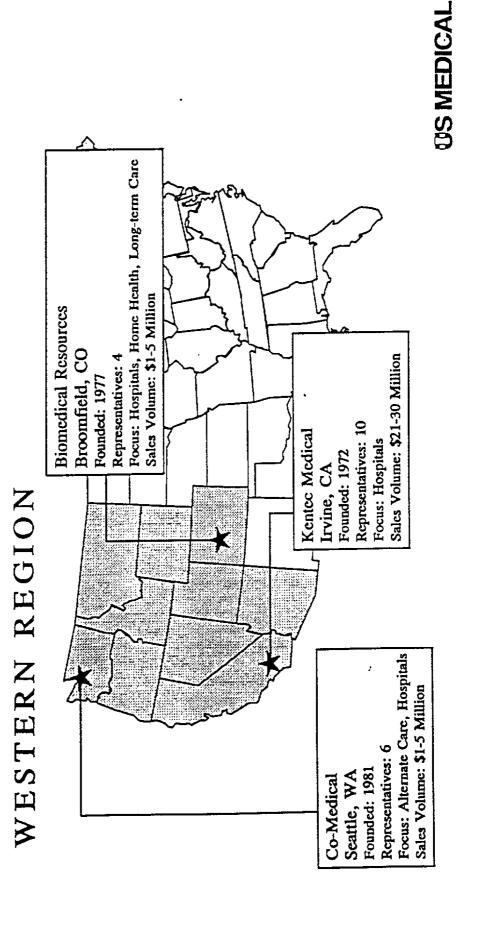
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COMPETITIVE PRODUCT MATRIX

Becton	Dickinson	YES	YES	YES	YES	YES	YES	YES	YES	YES		YES		YES			
Sherwood	Medical	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES				YES	YES	YES
N.S.	Medical				YES	YES	YES	YES	YES		YES	YES	YES	0			
		29G 1/2"	27G 1/2"	25G 5/8"	Syringe Only	25G 5/8"	· 23G 1"	22G 1 1/2"	22G 1"	21G 1 1/2"	21G 1"	Syringe Only	22G 1"	Syringe Only	Syringe Only	21G 1 1/2"	20G 1 1/2"
	Syringe Size	1cc Insulin 29G 1/2"	1cc Tuberculin		300							500		10cc	12cc		

☐ Available December 1 ○ Available September 15

Master Distributors



Master Distributors

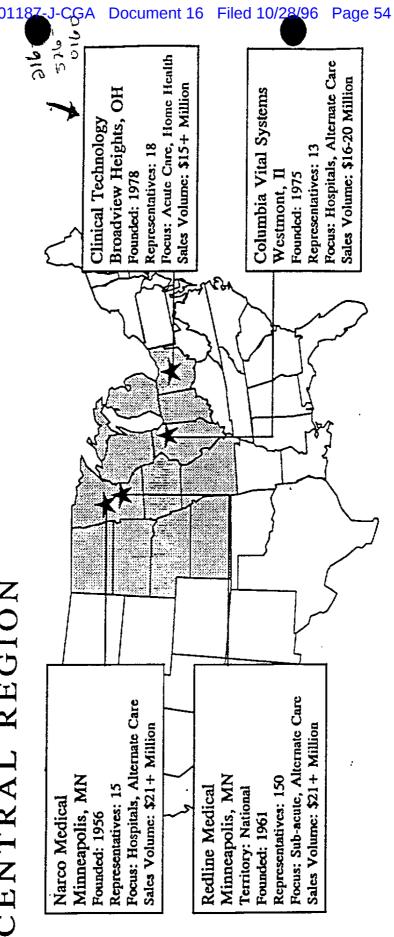
Representatives: 17 Founded: 1972

Bio-Systems Dallas, TX

OS MEDICAL

Master Distributors

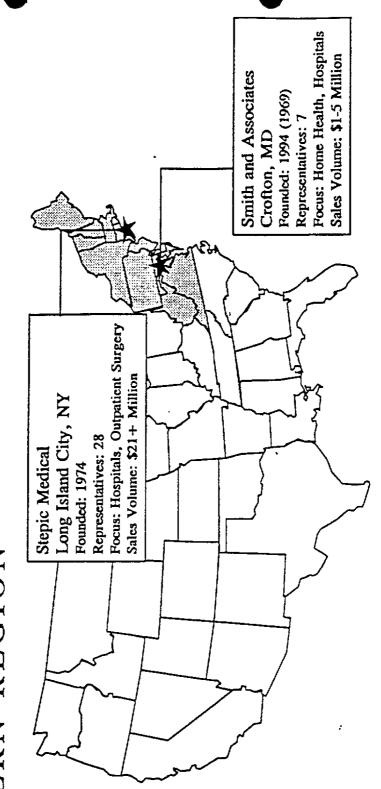
CENTRAL REGION



Master Distributors

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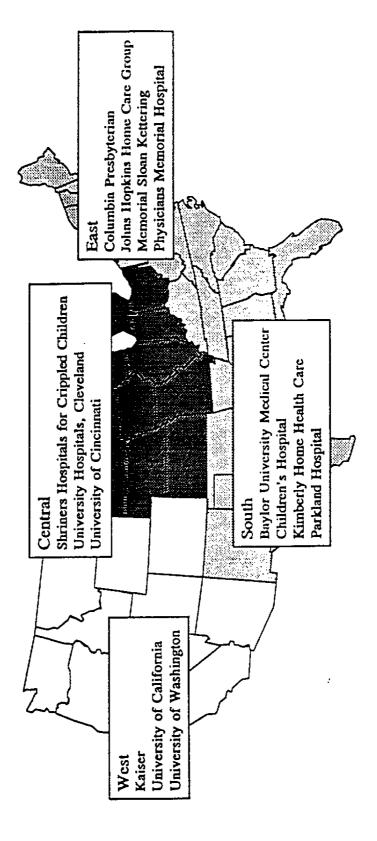
EASTERN REGION



WS MEDICAL

Master Distributors

REGIONAL KEY ACCOUNTS



US MEDICAL

III. Management

III. Management

The Company presently has approximately 50 full-time employees. The management team brings together tremendous experience in medical device manufacturing, sales and distribution, and market entrance experience. The Company's supporting professional services are as follows:

Supporting Professional Services

General Legal Counsel:

Wilson, Sonsini, Goodrich & Rosati, Palo Alto Brown, Martin, Haller & McClain, San Diego

Patent Counsel:

Merchant & Gould, Minneapolis

Patent Counsel: Accounting Services:

Price Waterhouse, San Diego

Board of Directors

Experience

Matthew S. Mazur

Chief Executive Officer, President and Founder of U.S. Medical Instruments, Inc. Over the past four years, Mr. Mazur has developed the proprietary product line and secured the necessary patent licenses needed to commercialize the product. Prior to forming U.S. Medical, Mr. Mazur was employed at Foothill Capital Corporation, a subsidiary of The Foothill Group. Mr. Mazur is a graduate of Brown University.

Carl Brown

Mr. Brown is a senior partner with U.S. Medical's patent firm of Brown, Martin, Haller and McClain. Mr. Brown has been an advisor of the company since its inception. Mr. Brown was recently named one of California's top ten attorneys, and has performed the legal patent work for various Fortune 500 companies.

James R. Yarter

Mr. Yarter is currently the Chief Executive Officer of Block Medical, Inc., a San Diego-based medical device manufacturer of I.V. infusion therapy products. Previously, Mr. Yarter was the President and Chief Executive Officer of Pancretec Inc., which was acquired in a 1989 by Abbott Labs for S54 million in an all-cash transaction. Mr. Yarter is presently on the Board of Directors of Menlo Care, Curaflex Inc. and Infrasonics.

George A. Schapiro

President, Sonic Force Corporation, a manufacturer of ultra-sonic force measuring instrumentation. Mr. Schapiro is a Director of 5 high-tech privately-held companies, and was recently the interim President of Hepatix, Inc. For 16 years prior he was President of Andros Inc., a NASDAQ-listed manufacturer of gas analyzers. Mr. Schapiro's broad experience includes serving as CEO of Novacor Medical Products Corporation (later acquired by Baxter Healthcare International), initial public offerings, private financings, and post-IPO transactions. Prior to Andros, Mr. Schapiro was a Product Market Manager for Hewlett-

George A. Schapiro (continued)

Packard, responsible for the patient monitoring product line. He has been a member of the Young President's Organization since 1984 and is a Director of the Anesthesia Patient Safety Foundation.

Key Management Experience

Matthew S. Mazur

Chief Executive Officer, and President. Over the past four years, Mr. Mazur has developed the proprietary product line and secured the necessary patent licenses needed to commercialize the product. Prior to forming U.S. Medical, Mr. Mazur was employed at Foothill Capital Corporation, a subsidiary of The Foothill Group. Mr. Mazur is a graduate of Brown University.

Ronald Bezincasa

Senior Vice President, Marketing and Sales. Mr. Benincasa was a founder of Intelligent Medical Systems, Inc. ("IMS") in 1982, which developed, manufactured and sold the first infrared tympanic membrane thermometer, FirstTempTM and the GeniusTM product lines. The Company was acquired by American Home Products in January 1993. Prior to his twelve year career at IMS, Mr. Benincasa headed the sales forces for companies including Wyeth-Ayerst Pharmaceuticals and Hoffman-LaRoche Laboratories. He holds a B.S. degree in Pharmacy and a Master of Science in Pharmacology from St. Johns University.

Carlos Manjarrez

Vice President, New Products, Research & Development. Mr. Manjarrez has been involved in the design and development of SafeSnap since the Company's inception. Previously, Mr. Manjarrez was Engineer and CAD Manager for Magor Molds, specializing in injection-molded medical products. His other experience includes being Design Engineer/Owner of Falcon Engineering specializing in high-precision medical designs, and as a Mold Designer for the Kipp Group.

David Faughnder

Vice President, Engineering. David Faughnder's career includes employment with three of the finest moldmakers in the United States. As Senior Design Engineer for The Kipp Group, Mr. Faughnder designed precision high-production injection molds for the medical industry. During his 10 year tenure he developed extensive experience with state-of-the-art runnerless mold systems and participated in special projects for medical applications. His prior experience with Dauntless Molds and Caco-Pacific Corporation was also spent specializing in the designing and building of precision high-production injection molds.

Charles E. Monts

Vice President, Finance and Administration. Mr. Monts, a licensed CPA, was most recently the Vice President/CFO of Overland Data, a San-Diego-based computer tape drive manufacturer. Overland Data grew during Mr. Monts' tenure from a \$3 million revenue base to over a \$35 million rate. During that six year period, the company completed two acquisitions and two venture capital financings. Prior to his

Charles E. Monts (continued)

employment at Overland Data, Mr. Monts held similar positions with companies in the electronics and publishing industries. His professional career began at Price Waterhouse as a Certified Public Accountant.

Sally Grigoriev

Vice President, Quality & Regulatory Affairs. Ms. Grigoriev recently joined U.S. Medical, bringing more than 12 years of experience in the medical device industry. Most recently she was responsible for the implementation of the entire regulatory and quality systems at Block Medical, Inc. a Class II critical device manufacturer of disposables and electronic infusion pumps. At Imed Corporation, also a Class II manufacturer of electronic infusion pumps and disposables, she held many positions including Manufacturing Engineering Manager-Plastics Molding and Sub-Assembly, Quality Assurance Manager-Plastics and Instruments Manufacturing. Ms. Grigoriev has a Bachelors of Science degree in Chemical Engineering from U.C. Santa Barbara, and is an ASQL Certified Quality Auditor.

Eugene Lim

Director of Manufacturing. Employed with U.S. Medical since 1992, Mr. Lim previously worked for Libbey Glass as Senior Process Engineer to design automated equipment and production mold tooling for the glass forming industry ranging from blow-molding, transfer and decorating machinery. Mr. Lim's extensive manufacturing experience includes the development of manufacturing processes and facilities with new products for large scale manufacturing; project management in Just-In-Time Environments; mold design, process piping design, PLC-based electrical control systems, and computer-aided design. Mr. Lim is a Mechanical and Manufacturing Engineer by education.

Ken Carstens

Materials Manager. Mr. Carstens previously spent six years as the Materials Manager for Camino Laboratories, a manufacturer of critical care disposables and electronic monitors for the neurosurgical market. At Camino, he was responsible for all materials management functions, including the implementation of their MRP II manufacturing system. Prior to Camino, Mr. Carstens spent twenty years in the U.S. Navy as a Supply Corps Officer, the Navy's equivalent to a materials manager. Mr. Carstens earned an MBA from the University of Michigan and a certificate in Purchasing Management from UCSD. He is certified in Production and Inventory Management by APICS and earned the title of Certified Purchasing Manager by NAPM.

IV. Financials

July 1994
nc.
Instruments,
Medical
U.S.

U.S. Medical Instruments, Inc.	FYE 1/31/95*	FYE 1/31/96*	FYE 1/31/97*
Pro Forma Income Statement Units Sold (millions)	29,000,000	144,000,000	300,000,000
USMI Revenues	\$7,250,000	\$25,920,000	\$42,000,000
Cost of Goods Sold	\$5,832,000	\$11,562,000	\$21,288,000
Gross Profit	\$1,418,000	\$14,358,000	\$20,712,000
Operating Expenses	\$2,379,000	\$3.830.400	<u>\$5,880,000</u>
Earnings Before Deprc., Int. & Taxes (EBDIT)	(\$961,000)	\$10,527,600	\$14,832,000
Depreciation & Amortization	\$626,000	\$1,219,000	\$1,268,000
Interest	\$425,000	\$843,000	\$1,446,000
PreTax Earnings	(\$2,012,000)	\$8,465,600	\$12,118,000
Taxes Net Income EPS (FY96 EPS includes 5,324,520 shares outstanding on 6/30/94, and assumes 1 million Series E Shares issued, and assumes 1 million shares from IPO at \$20.00/share)	\$0	\$1,0 <u>97,928</u>	\$4,367,000
	(\$2,012,000)	\$7,367,672	\$7,751,000
	NA	\$1.01	\$1.06

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Value/Share	\$29.12
Valuation	\$184,191,800
P/E Multiple	25
EYE '96 EPS	\$1.01

* The U.S. Medical Fiscal Year Ends on January 31

U.S. Medical Instruments, Inc. Sources and Uses of Funds From Series E Preferred Shares

Sources:	<u>Total Dollars</u>
1 million Series E Preferred Shares @ \$7.50/share.	\$7,500,000
Total Sources	\$7,500,000
Uses:	
Injection molds, automation machinery & equipment	\$2,730,000
Expansion/Leasehold Improvements	\$2,200,000
Working Capital	\$1,950,000
Total Uses	\$6,880,000
Net Excess Funds	\$620,000

U.S. Medical Instruments, Inc. Sources and Uses of Funds From Initial Public Offering

Sources:	Total Dollars
Funds from IPO: 1 Million Shares @ \$20.00/share.	\$20,000,000
Total Sources	\$20,000,000
Uses: Injection molds, automation machinery & equipment	\$8,217,500
Expansion/Leasehold Improvements	\$2,750,000
Working Capital	\$4,757,500
New Product Development	\$4,275,000
Total Uses	\$20,000,000
Net Excess Funds	\$0

V. Investment Considerations

U.S. MEDICAL AFTER MARKET INCOME:

- Technology Transfer Fee (Japan, Taiwan)
- Mold Making for 1cc, 3cc, 5cc and 10cc SafeSnap Molds for Foreign Licensors
- Royalty Income
- New Products

U.S. MEDICAL NEW PRODUCTS:

- Winged Butterfly Catheters

- Vial Adapters

- Safety Arteriovenous Fistula Needles

- Blood Gas Syringes

PROFITABILITY:

- Gross Margins in Excess of 50%
- High-Volumes Permit Strong Return on Assets
- Low Overhead
- SafeSnap is Attractive to International Licensors
- Distributors have Extra Profit Incentive to Move the Product

THE PRODUCT:

- The Best Safety Syringe Design on the Market.
- SafeSnap Can Be Sold for as High as \$0.49/Unit (vs \$0.10-\$0.12/Unit for non-safety syringes)
- Syringes are "Anchor" Products, Facilitating Market Entry for Encore Product Lines
- Cost to Manufacture is Competitive With Generic Syringe
- Strong Patent Protection

THE MARKET:

- 5 Billion Syringes are Used in the U.S. Annually, 18 to 20 Billion Worldwide.
- Safety Syringes are Projected to Obtain 75% of All U.S. Syringe Sales by 1997 (Theta Corporation, January 1994)
- AIDS, Hepatitis B, and Other Infectious Diseases are Omnipresent.
- Needlesticks are the Most Frequent Injuries in the Healthcare Environment

THE COMPANY:

- Well-Positioned
- Innovative, Experienced Management
- Leading Edge Technology
- New Related Product Lines Under Development
- Expansion Becomes Cookie-Cutter
- Capital Intensity of High-Volume Facility is Significant Barrier to Entry

Case 3:96-cv-0stant-dagGGCONPULTION, 16ATE PAUG 28/96, 159 ge 72 of 212 2,000 SHARES SERIES E PREFERRAL STOCK

U.S. Medical Instruments, Inc. Series E Preferred Stock Private Placement Memorandum

All of the 2,000,000 shares of Series E Preferred Stock ("Series E") offered hereby being sold by U.S. Medical Instruments, Inc. ("U.S. Medical" or the "Company"). Prior to this private placement offering ("Offering"), there has been no public market for the Company's Common Stock, Series A Preferred Stock, Series B Preferred Stock, Series C Preferred Stock or Series D Preferred Stock. Similarly, the Series E shares in this Offering will not be traded on any public exchange.

The shares of this Offering must be held indefinitely unless subsequently registered under the Securities Act or an exemption from such registration is available. The provisions of Rule 144 promulgated under the Securities Act permit limited resale of shares purchased in a private placement subject to the satisfaction of certain conditions, including, among other things, the existence of a public market for the shares, the availability of certain current public information about the Company, the resale occurring not less than two years after a party has purchased and paid for the security to be sold, the sale being effected through a "broker's transaction" or in transactions directly with a "market maker."

It is currently anticipated that the Series E price per share will be \$7.50 per share; that the shares will be sold in Units, whereby 1 Unit equals \$112,500.00, or 15,000.00 shares; and that the maximum number of Units sold will be 133 Units. Closings may take place when the Company has raised a minimum of \$1.500,000.00 and \$3,000,000.00. All dollars will be escrowed in the interim at First Interstate Bank, 701 B Street, San Diego, California, 92101.

The Company has 6 classes of stock. The Series E offered hereby entitles its holders to one vote per share, as do the other 5 classes of stock. See "Capital Structure". An investment in the shares of Series E offered hereby involves a high degree of risk. See "Risk Factors."

THESE SECURITIES HAVE NOT BEEN APPROVED OR DISAPPROVED BY THE SECURITIES AND EXCHANGE COMMISSION OR ANY STATE SECURITIES COMMISSION NOR HAS THE SECURITIES AND EXCHANGE COMMISSION OR ANY STATE SECURITIES COMMISSION PASSED UPON THE ACCURACY OR ADEQUACY OF THIS PROSPECTUS. ANY REPRESENTATION TO THE CONTRARY IS A CRIMINAL OFFENSE.

	Price to Private Investor	Underwriting Discount (1)	Proceeds to Company (2)
Per Share	\$7.50	\$0.375	\$7.125
Per Unit	\$112,500.00	\$5625.00	\$106,875,000
Total (3)	\$15,000,000.00	\$750,000.00	\$14,250,000,00

(1) For information regarding indemnification of the Underwriters and certain compensation payable to the Representative of the Underwriters (The "Representative"), see "Underwriting".

(2) Before deducting expenses of the Offering payable by the Company estimated at \$750,000.

The Series E Preferred Shares are offered by U.S. Medical Instruments, Inc. subject to prior sale, receipt and acceptance by them and subject to their right to reject orders in whole or in part and to certain other conditions. It is expected that certificates for such shares will be available for delivery on or about October 31, 1994.

The date of this Prospectus is August 15, 1994

information contained herein is subject to completion or amendment. This propsepactus shall not constitute an offer to sell or the sociation of an offer to buy nor shall there be any sale of these securities in any State in which such offer, solicitation or sale would be unlawful prior to registrating or qualification under the securities laws of any such State.

If there was a product that could help prevent accidental needle sticks and transmission of infectious diseases...

Wouldn't you use it?

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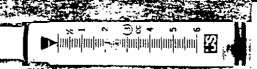
SafeSnap_m

Retractable Needle Safety Syringe

TURN THIS



INTO THIS



USMEDICAL

Instruments, Inc.

Retractable Needle Safety Syringe DESCRIPTION REORDER# QUANTITY 11730 3cc & 6cc 20G 1&1/2 100 units/box 3cc & 6cc 22G 1&1/2 11710 100 units/box 11720 3cc & 6cc 25G 5/8 100 units/box 3cc & 6cc No Needle 11700 100 units/box

FEATURES & BENEFITS

■ Retractable Needle - Reduces Needlesticks

- Reduces Medical Waste Hazard

- Maximizes Sharps Container Usage

■ 3cc/6cc Design - Reduces Inventory; Cost Efficient

■ International Color Coding - Allows Quick Recognition and Coordination

With Needle

■ User Friendly - Standard Injection Protocol Can Be Used With

Minimal In-Servicing

■ Cost Competitive - Reduces Costs of Medical Testing, Treatment,

Patent Pending

Counselling, Nurses' Downtime, & Potential

Made in the USA

Legal Liability

P.O. # Reorder # Quantity

FDA Approved

For information regarding other sizes contact a U.S. Medical Instruments Sales Representative,



3500 ESTUDILLO STREET • SAN DIEGO, CA 92110 • (619) 291-7900 • FAX: (619) 291-8800

PRIVATE PLACEMENT MEMORANDUM SUMMARY

The following summary should be read in conjunction with and is qualified in its entirely by the more detailed information, financial statements and notes thereto appearing elsewhere in this Prospectus.

The Company. U.S. Medical Instruments, Inc., ("U.S. Medical" or the "Company"), is a technology-based medical device manufacturer with the mission of developing, manufacturing and marketing safety-enhanced medical instruments that are both cost-effective and user-friendly. The California corporation's first product is SafeSnapTM, a patented line of single-use hypodermic syringes that will substantially reduce the incidence of accidental needlesticks in the healthcare and homecare markets. The technically and aesthetically superior high-precision SafeSnap design is unlike any other syringe available on the market, in that it permits the used needle to retract into the syringe barrel, completely shielding the needle from human contact. Management intends to capture at least five percent of the more than 5 billion unit annual U.S. syringe market over the next three years, and use the resulting income and manufacturing capabilities as a platform for launching other safety-enhanced medical devices. Follow-on products include safety winged-butterfly catheters, vial adapters, safety arteriovenous fistula needles, and blood-gas syringes, currently in their early stages of development. Revenue from the core SafeSnap business is projected to reach \$48 million by the fiscal year ended January 31, 1997, with gross margins in excess of 50%.

Market Overview. Syringes are an integral part of modern medical practice and procedure. They are used by virtually every hospital, doctor's office and medical clinic in their delivery of medical care, for diagnostic testing, and for other health-related purposes. Syringes can be broadly categorized as generic, or standard syringes and safety syringes. Standard syringes are designed to perform specific medical functions, while safety syringes are designed to perform those same functions while reducing the risk of accidental needlesticks.

Accidental needlesticks may result in the spread of infectious diseases such as Hepatitis B and the Human Immuno-deficiency Virus ("HIV") which may lead to Acquired Immune Deficiency Syndrome ("AIDS"). The Center for Disease Control reports that 12,000 needle stick injuries are reported in the healthcare environment nationally each year, and there is reason to believe that this number actually represents only half of all needlestick incidents. A needlestick results in direct costs of up to \$1,200 per incident for treatment of the wound, diagnostic tests, and lost worker time. Other potential costs may include specialized, long-term treatment and potential hability costs, as well as the need for a replacement. Reported deaths from contraction of Hepatitis B through needle sticks exceed 250 annually, while the number of total sticks leading to death by AIDS exceeds 36. Expensive and reputation-damaging lawsuits by victims of sticks, along with mounting pressure from regulators and lawmakers (e.g. excise tax proposed for non-safety syringes) is driving healthcare organizations to examine safety syringe alternatives.

14400,000

The disposable hypodermic syringe represents the single largest segment of medical instrumentation in terms of units used, with more than 16 billion sold world wide annually, 4.6 billion in the U.S. alone in 1993. Due to universal concern over infectious diseases transmitted by reusable needles and syringes, worldwide syringe growth has been approximately 15% over the past few years and is expected to continue at that pace, as expressed in Becton Dickinson's 1991 Shareholders' Annual Report.

Independent industry studies estimated that safety syringes currently represent approximately 15% of the domestic syringe market, and may represent as much as 80% of the market within the next 5 years. (Theta Corporation, January 1994 Report #346 Medical Needles & Syringes). The Company believes that its SafeSnap syringes, because of their significant advantages over other safety syringes and standard syringes, have the potential to capture a significant share of the overall syringe market. The SafeSnap

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syringe is similar in appearance, size, performance and general operation to standard syringes and works with substantially all standard syringe accessories.

The Product. The SafeSnap design permits the used needle to retract into the barrel of the syringe, shielding it from human contact and preventing re-use. Furthermore, the plunger rod is designed to be broken off once the needle is fully retracted, at which point it is inserted into the front end of the barrel - thus the syringe is no longer usable and the needle is completely enclosed within the barrel. In effect, the syringe has transformed into a permanent sharps container for the contaminated needle. Since the distinction in design is internal, SafeSnap requires limited technique change and appears aesthetically similar to non-protective syringes.

Besides U.S. Medical, Becton Dickinson and Sherwood Medical are the two principal companies selling safety syringes. Safety syringes have already established premium pricing of three to five times that of generic syringes. While SafeSnap is superior in design to other safety syringes, it has the distinguishable cost benefit of a generic syringe's manufacturing cost with a premium sales price. Furthermore, in market evaluations conducted by several healthcare organizations nationwide, nurses have expressed an overwhelming preference for SafeSnap over the safety syringes sold by B-D and Sherwood. The patented SafeSnap safety syringe has the following features:

Maximum Security, Minimum Risk: The design of the SafeSnap Syringe, which permits the used needle to retract into the barrel to completely shield it from human contact, providing a level of safety never before available.

Cost Effective: The reduction of needlestick injuries greatly reduces the cost of providing healthcare services.

<u>User Friendly:</u> Allows nurses to utilize standard injection technique in giving injections.

Medical Waste Protection: Reduces liability in the work environment as well as during the transportation to the final disposal destination. Also, reduces potential hazards in the event of improper disposal.

Single Use: SafeSnap is not reusable, and thus satisfies the requirements set forth by organizations such as the CDC. WHO and OSHA that competitive safety "sheath" devices do not. Sheath safety syringes presently for sale can be utilized again with the removal of the sheath.

Product Cost: SafeSnap syringes can be sold at prices comparable to or lower than other safety syringes.

Full Product Line: The SafeSnap product line will include several calibration sizes of syringes, permitting full conversions and purchasing syringes from one manufacturer.

Color Coded Packaging: Quick product identification saves time, allowing universal recognition.

Luer Lock Needle Holder: Permits user to employ needle brand and needle size of choice.

The SafeSnap syringe, however, is more expensive than standard syringes, does not completely eliminate the risk of accidental needlesticks, and has not yet gained full market acceptance. See "Risk Factors."

Company Objective. The Company's objective is to establish itself as a leading provider of safety syringes and related medical sharps devices. To achieve this objective, the Company's growth strategy is focused on the following four principal elements: (i) capturing as much as 5 percent of the syringe market within the next three years, with continual rapid growth thereafter (ii) continued timely expansion of the Company's production capacity to facilitate demand; (iii) broadening the Company's product lines to increase market penetration into closely related markets (safety winged-butterfly eatheters, vial adapters, safety arteriovenous fistula needles, and blood-gas syringes); and (iv) seeking additional market opportunities, domestically and internationally, based on the Company's proprietary technology.

SERIES E PREFERRED PRIVATE PLACEMENT ed 10/28/96 Page 78 of 212 Case 3:96-cv-01187-J-CGA Document 16 Filed 10/2

spectus, the term "safety syringe" refers to (i) a safety medical device which is a syringe with or without an attached needle and (ii) a safety medical device whereby the principal components may include related and ancillary parts whose purpose is to shield or protect the needle from human contact or puncture.

Sales & Marketing. The domestic syringe market can be divided into three segments: hospitals; alternate care; and physician offices. Management has selected to penetrate these segments with the aid of distributor alliances and independent sales organizations. The primary market penetizion strategy employed is to provide enough SafeSnap for organizations to conduct their own independent evaluations, while providing a thorough in-service program to the users. Many evaluations have been completed in Southern California, most of which have led to the demand for hospital and clinic conversions.

The 3cc and 5cc SafeSnap syringe sizes are currently available for sale. These two sizes account for approximately, 60 percent of this market. U.S. Medical's recent boost in production capacity will permit the Company and its distributors to launch marketing and sales campaigns with the confidence that it can supply the anticipated demand. Management anticipates that the 10cc and 1cc SafeSnap sizes will be prepared for market during the third and fourth quarters of fiscal 1995.

U.S. Medical has recently formed alliances with 12 medical device master distributors, whose combined territories cover all 50 of the American states. These master distributors, comprising 250 specialty medical sales representatives, have primary responsibility for Acute Care/Subacute Cae facilitues. They are also permitted to arrange for access to Alternate Site customers (including home exe), a market sector well-known for its paying of premium pricing.

U.S. Medical recently attended the Intravenous Nurses Society's National Convention ("INS") in Denver, as well as the American Association of Critical Care Nurses' National Convention ("NTI/CCN") in Atlanta and the Association of Practitioners of Infection Control ("APIC") in Cincinatti. At all three of these shows, SafeSnap received significant praise and attention, generating more than 500 solid leads for samples and requests for sales visits.

Several additional marketing opportunities are currently under discussion with recognizable healthcare concerns and international organizations, including distribution agreements, pre-packaging of SafeSnap with other products in kits, OEM supplying & private labeling, pre-filling, and international licensing agreements.

Patents and Trademarks. U.S. Medical owns the exclusive right to make, use and sell the proprietary property of patents pending covering the SafeSnap design and all designs associated with the development of this product. The first two patents of the several filed were assigned U.S. Nos. 5,205,824 and 5,308,329, and were issued in April, 1993 and May, 1994, respectively. U.S. Medical's patent position is further strengthened with the exclusive licensing of certain key patents. The combination of these issued patents, in addition to the Company's patents still pending, represent a significant competitive barrier in the retractable safety syringe industry.

"SafeSnap"" and "U.S. Medical Instruments, Inc." are registered trademarks of the Company.

Production. U.S. Medical is registered with the U.S. FDA as a medical device manufacturer. The Company's 52,000 square foot facility in Rancho Bernardo, leased from McDonnell Dougls, is extremely well-suited for its expansion of production capacity through fiscal 1997 (the Company's fiscal year ends January 31). The facility is designed to be vertically integrated, with design, mold-making, manufacturing, assembly and packaging all in the same facility.

High-precision stainless steel syringe molds are the core of the Company's production process. A well-designed, well-built mold will maximize raw material utilization, minimize the cycle time, hold to the strictest tolerances, and last for as long as fifteen years. The more cavitations in a mold be greater the

SERIES E PREFERRED PRIVATE PLACEMENT

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volume capacity per come. The Company believes that the expense, the and proprietary technology required to build similar molds and create prototypes is a strong barrier to competition entering this market segment.

U.S. Medical presently has the production capacity to produce the molded parts for at least five million units per month. Until the already-on-order high-speed assembly automation equipment arrives in the fourth quarter of fiscal 1995, assembly operations will be conducted solely at the Nypro Precision Assemblies, Inc. Macqiladora facility under a subcontracting agreement. Working with Nypro's facility in Mexico permits U.S. Medical to meet its fiscal 1995 objectives to sell 29 million units. While production capacity for fiscal 1995 will be greater than this 29 million units, Management prefers to invest all capital raised in high-speed equipment and preparation for long term profitability, rather than on sub-assembly costs. The implementation of high-speed assembly automation will permit the Company to immediately maximize the efficiency of the production process, as well as recognize cost savings associated with economies of scale.

The Company anticipates that additional sets of high-cavitational molds and high speed assembly and packaging automation will come on-line throughout fiscal 1996 and 1997 such that total production capacity will be 144 million units and 300 million units, respectively.

Financing. To date, the Company has financed its operations principally through private placements of equity securities. More than \$11 million of seed capital has been raised since the Company's inception. Investment capital is presently being sought in the amount of \$15 million. The new capital would be applied toward the purchase of additional sets of molds, additional injection molding machines, assembly and packaging automation equipment and working capital required to meet the Company's business plan.

The Company was incorporated in California in June, 1991. The Company's offices are located at 16825 Via del Campo Court, San Diego (Rancho Bernardo), California 92127. The Company's telephone numbers are (619) 674-7200 and (800) SAFESNAP.

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Needlestick Legislation

SERVES E PREFERRED PROSPER SERVENT

Preferred Stock Offered: Series E Preferred Stock

2,000,000 shares Offered hereby

-at \$7.50 per share
- to be sold in Units of \$112,500

Outstanding prior to the Offering on August 1, 1994:

Common Stock 1,617,532 shares
Series A Preferred Stock 1,332,000 shares
Series B Preferred Stock 779,195 shares
Series C Preferred Stock 205,933 shares
Series D Preferred Stock 1,589,196 shares
Total Pre-Offering Shares Outstanding 5,523,856 shares

Total Post-Offering Shares, Common and all Series 7,523,856 shares

Use of Proceeds. Purchase of capital equipment for the continued development of manufacturing systems; continued research, development and testing of new products; expansion of sales and marketing efforts; and other general corporate purposes. See "Use of Proceeds".

Underwriter. For purposes of this Offering it is assumed that any registered "broker-dealer" responsible for raising the funds will receive a commission based upon a formula frequently used in private placement transactions. The commission will be deducted from total proceeds to the Company from the Offering.

Sophisticated Investor. In order to subscribe to this Offering the interested party must qualify as a "sophisticated investor" according to Securities Law. See "Addendum X: Series E Stock Purchase Agreement".

Other. The Company may terminate this Offering prior to issuance of all Series E Shares offered hereby.

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USE OF PROCEEDS:

The net proceeds to the Company from the sale of the 2,000,000 shares of Series E PreferredStock being offered hereby are estimated to be \$14,250,000, assuming a private placement offering price of \$7.50 per share and after deducting estimated underwriting commissions and legal expenses of the Offering. The net proceeds are expected to be used as follows (amounts are approximate):

- (i) \$2.8 million will be used to purchase capital equipment, including molds, automation equipment and production machinery;
- (ii) S3 million will be used to continue the Company's facility expansion and leasehold improvements
 - (iii) S2 million will be used for development of additional product lines
- (iv) \$4 million will be used for working capital and to support general operations and research and development of the Company

TOTAL USE OF FUNDS: \$11,800,000

The allocations set forth above are subject to change based upon actual rather than estimated expenses and changes in business conditions. Pending use of the proceeds as described above, the net proceeds will be invested in bank deposits and short-term, investment grade securities, including government obligations and money market instruments.

See "Section X, Financial Projections" of the August 1994 Business Plan included in this Memorandum, as well as "Management's Discussion and Analysis of Financial Condition and Results of Operations." The Company anticipates that such funds will be sufficient to support the Company's operations and planned capital expenditures through at least June 30, 1995.

RISK FACTORS

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In addition to the other information in this Prospectus, the following factors should be considered carefully by potential purchasers in evaluating an investment in the shares of Common Stock offered hereby:

Development Stage Company History of Losses Uncertain Profitability. The Company is a development stage company with limited sales of its first product, the SafeSnap safety syringe. The Company has experienced annual operating losses and negative operating cash flow since its incorporation in 1991. At January 31, 1994, the Company's fiscal 1994 year end, U.S. Medical had an accumulated deficit of approximately \$5.68 million. Although management believes that the Company will achieve profitability as soon as late in fiscal 1995, there is no assurance that the Company will be able to operate profitably. The Company will have difficulties normally encountered by a new enterprise in its development stage, many of which are beyond the Company's control, and there is nothing at this time upon to base an assumption that the Company's proposed business plans will either materialize or prove successful.

Limited Manufacturing Experience. The Company has limited manufacturing experience. Sales of the Company's only commercial products, the SafeSnap 3cc and 5cc syringes, began in May of 1994, and are currently limited by the Company's manufacturing capacity. The Company is continuing to improve and refine its manufacturing processes. For the Company to be successful, it must manufacture SafeSnap syringes in sufficient quantities, to rigorous quality control standards- and at a masoriable cost. The Company's failure either to produce sufficient quantities of the product or to manufacture the product at or near its estimated cost per unit while meeting the appropriate quality control standards could have a material adverse effect on the Company.

Dependence on a Single Technology. The Company's strategy is to first develop and manufacture additional safety syringes including the 1cc and 10cc sizes, to be followed by new sharps safety devices. The initial focus on a single product line and technology makes the Company vulnerable to the development of superior competing products and changes in technology which could eliminate the need for the Company's products. While the Company believes there will be no significant change in the foreseeable future in the need for the Company's products or the desirability of those products, there can be no assurance that such change will not occur.

Dependence on Key Suppliers and Assemblers. The Company purchases its needles from a single source. Several of the SafeSnap syringe's required raw materials are also purchase from single sources. In addition, until the high-speed assembly automation is delivered beginning less fiscal 1995, the Company will rely upon a sub assembly subcontractors, Nypro Precision Assembles and Kendall Healthcare, to assemble the syringes. The Company could establish alternative suppliers and assembly arrangements if necessary. However, changes could disrupt production schedules and could have a material adverse effect on the Company. The Company's needle supplier is located in a frester country. In addition to the normal risks associated with changes in suppliers' prices, the cost of the needle could be adversely affected by changes in currency exchange rates.

Lack of Full Market Acceptance. The use of safety medical products, including safety syringes, is relatively new. Furthermore, the sale of sub-par safety syringes to date may have created some market resistance to all safety syringe designs. Although the market for syringes is large, actual sales of the Company's products may be much less than the market's potential. Market acceptance of the Company's products will depend in large part upon the Company's ability to demonstrate the operational advantages, safety and cost effectiveness of its products compared to standard syringes and its competitors' safety syringes. The higher cost of the Company's products may be an impediment to market acceptance, but the Company does not believe that price will be a significant factor in achieving market acceptance. There can be no assurance that the Company's products will achieve full market acceptance.

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Dependence on Continued Research and Development. The Company is exploring other applications for its patented retractable needle technology beyond the SafeSnap syringe. In addition, the Company is continuing its research and development of new technologies to provide safer medical devices, and is also considering the licensing of several new technologies from outside sources. The development of additional applications and additional products may be important to the longer-term success of the Company. There can be no assurance that any of such applications or products will be developed, or that they will be successful. There can be no assurance that the development of new products mentioned in this Prospectus will be completed on schedule, that clinical trials of any of the products, when undertaken, will be successful, or that there will be a significant demand for any of the products once development is completed.

Dependence on Patents and Proprietary Rights. The Company's future success depends in part on its ability to protect its intellectual property and maintain the proprietary nature of its technology through a combination of patents and other intellectual property arrangements. The Company has been granted two U.S. patents which are directly applicable to the SafeSnap syringe, and has obtained corresponding patents for its retractable needle syringe technology in a number of countries and has patent applications pending in certain other countries. See "Business - Patents and Proprietary Rights."

U.S. Medical's patent position is further strengthened with the exclusive licensing of key patents. The combination of these issued patents, in addition to the Company's patents still pending, represent a significant competitive barrier in the retractable safety syringe industry. The Company believes such patents will be sufficient to protect the structure and design of its current and proposed products. However, there can be no assurance that the protection provided by such patents will be broad enough to prevent competitors from introducing similar devices or that such patents, if challenged, will be upheld by the courts of any jurisdiction. Patent infringement litigation, either to enforce the Company's patents or defend the Company from patent infringement suits, would be expensive, and if it occurs, could divert Company resources from other planned uses. Further, any adverse outcome in such litigation could have a material adverse effect on the Company.

In addition, patent applications filed in foreign countries and patents granted in such countries are subject to laws, rules and procedures which differ from those in the United States. Patent protection in such countries may be different from patent protection provided by U.S. laws and may not be as favorable to the Company. The Company also attempts to protect its proprietary information through the use of employee confidentiality agreements and by limiting access to its facilities. There can be no 'assurance that the Company's program of patent protection, confidentiality agreements and restricted access to its facilities will be sufficient to protect the Company's proprietary technology from competitors.

Ability to Manage Growth. The Company intends to pursue a strategy of rapid growth. The Company plans to significantly expand production and to devote substantial resources to research and development and operational support areas, including marketing and administrative services. There can be no assurance that the Company will be able to attract qualified personnel or successfully manage such expanded operations. The failure to properly manage growth could have a material adverse effect on the Company.

Competition. The syringe market is highly competitive. The leading manufacturers of standard syringes are Becton-Dickinson and Sherwood Medical Company, Inc., a subsidiary of American Home Products Corporation, and Terumo Medical Corporation of Japan. Two of these companies (Becton-Dickinson and Sherwood) also manufacture safety syringes. There are also numerous smaller manufacturers of safety syringes and safety needles. The Company believes that its SafeSnap syringe design is superior to all safety syringes on the market today, and that it can compete effectively against safety and standard syringes based upon the SafeSnap syringe's innovative design, quality and

convenience of use. However, the Company's primary competitors have longer operating histories and are substantially larger, better financed and better situated in the market than the Company. Such competitors may use their economic strength to influence the market to continue to buy their existing products. One or more of these competitors also could use such resources to improve their current products or develop new products which may compete more effectively with the Company's products. New competitors may arise and may develop products which compete with the Company's products. In addition, new technologies may arise which could lower or eliminate the demand for the Company's products.

The Company may pursue additional businesses that are characterized by intense competition among numerous companies, many of whom have far better resources than the Company and there is no assurance that the Company will be able to effectively compete with its competitors.

Need for Additional Funds. The proceeds from the Offering will not be sufficient to enable the Company to carry out its porposed objectives and the Company will require additional financing and there is no assurance that the Company will obtain any additional financings or, if available, that such additional financings will be obtained on terms satisfactory to the Company. The Company's need for capital during the next year or more will vary based upon a number of factors, including the rate at which production capacity is expanded, the level of sales and marketing activities for the SafeSnap syringe, and the level of effort needed to develop new products to the point of commercial viability.

Product Liability. The manufacture and sale of medical devices entails an inherent risk of liability in the event of product failure or claim of harm caused by product operation. The Company is not aware of any claim against it based upon the use or the failure of its safety syringes. The Company maintains product liability insurance against any such claims in amounts it believes to be adequate. There can be no assurance that the Company will not be subject to such claims, that any claim be successfully defended, or if the Company is found liable, that the claim will not exceed the limits of the Company's insurance. There is also no assurance that the Company will be able to continue to obtain product liability insurance with acceptable terms. Product liability claims could have a material adverse effect on the Company.

Limited Manufacturing Facilities. The Company's current facilities do not have sufficient space to accommodate the expansion of manufacturing operations beyond the 30 million units per month figure projected to be attained during fiscal 1997.

Government Regulation. Government regulation is a significant factor in the development and marketing of the Company's products and in the Company's ongoing manufacturing and research and development activities.

The Company's safety syringe is a Class II device under the regulatory structure of the Federal Food, Drug, and Cosmetic Act (the "FDC Act") which is administered by the United Stress Food and Drug Administration ("FDA"). The Company is free to market and sell the SafeSnap syringe subject to ongoing regulatory controls by the FDA. Among other things, the FDA requires the Company to adhere to certain "Good Manufacturing Practices" ("GMP") regulations which include validation testing, quality assurance, quality control and documentation procedures. The Company's facilities are also subject to periodic inspections. As a Class II device, performance standards may be developed for the safety syringe which the product would then be required to meet. Failure to meet those standards would require the Company to discontinue the marketing of the product. In addition, future regulations may be imposed which might have a material adverse effect on the Company and/or one or more of its products. Furthermore, since the FDA continually regulates and inspects medical devices and their manufacture, any actual or potential product failure could result in the imposition of administrative and/or judicial sanctions, including product recall, which might have a material adverse effect on the Company.

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The Company other products (safety winged-butterfly eters, vial adapters, safety arteriovenous fistula needles, and blood-gas syringes) are still in the development stage and have not been classified by the FDA. The Company expects such products to be Class II devices and to be subject to the same types of limitations and controls as its SafeSnap syringe.

Distribution of the Company's products in countries other than the United States may be subject to regulation in those countries. There can be no assurance that the Company will be able to obtain the approvals necessary to market its safety syringes or any other product outside of the United States.

Dependence on Key Personnel. The success of the Company depends upon the skills, experience and efforts of its executive officers and certain marketing and technical, people. The Company is particularly dependent upon the services of Matthew S. Mazur, its Chief Executive Officer, President and Founder. The loss of the services of Mr. Mazur or any of the Company's other key personnel could have a material adverse effect on the Company. The Company does have employment agreements with Mr. Mazur as well as all other key employees.

No Public Market. No public market now exists for any of the securities issued by the Company, that the Company has made no assurances that a public market will ever exist for the Shares, and that, even if such a public market exists at some future time, the Company may not then be satisfying the current public information requirements of Rule 144.

Rule 144 The shares of this Offering must be held indefinitely unless subsequently registered under the Securities Act or an exemption from such registration is available. The provisions of Rule 144 promulgated under the Securities Act which permit limited resale of shares purchased in a private placement subject to the satisfaction of certain conditions, including, among other things, the existence of a public market for the shares, the availability of certain current public information about the Company, the resale occurring not less than two years after a party has purchased and paid for the security to be sold, the sale being effected through a "broker's transaction" or in transcations directly with a "market maker" (as provided by Rule 144(f) and the number of shares being sold during any three-month period not exceeding specific limitations.

Dilution. The private placement price is substantially higher than the net tangible book value per share (including Common Stock and all Preferred Stock). Investors purchasing shares the Offering will therefore incur immediate, substantial dilution. See "Dilution." In addition, certain investors and members of the Company's management hold warrants to purchase a substantial number of shares of Common Stock, which warrants are currently exercisable at a price below the private placement offering price.

Further dilution also may be experienced should the Company raise additional funds after the Offering through the sale of equity securities.

No Dividends. The Company has not paid any dividends since its inception and does not intend to pay any dividends for the foreseeable future. See "Dividend Policy."

CAPITAL STRUCTURE

Capitalization

The following table sets forth as of August 1, 1994: (i) the actual capitalization of the Company; (ii) such pro forma capitalization as adjusted to give effect to the sale of 2,000,000 shares of Common Stock offered hereby at a private placement offering price of \$7.50 per share, less applicable underwriting discount and estimated offering expenses payable by the Company.

The Company has 6 classes of stock, including one class of Common Stock, and five classes of Preferred Stock. Each share of Series A, B, C, and D Preferred Stock is initially convertible into one share of Common Stock at the option of the shareholder, at any time prior to redemption by the Company or automatic conversion. The conversion rate is subject to adjustment in the event of a stock split or stock dividend. The Series A through D Preferred Stock has voting rights which are identical to the Common stock voting rights, and automatically converts into shares of Common Stock immediately upon an initial public offering which results in gross proceeds to the Company exceeding \$3,000,000. The Series E Preferred Shares hereby offered have similar voting and conversion rights as the Series A through D Preferred Stock.

In the event of any liquidation, dissolution, or winding up of the Company, the holders of Series A, B, C, D and E Preferred Stock shall be entitles to receive, prior and in preference to any distribution of any assets to the common shareholders, an amount per share equal to \$0.02, \$2.10, \$2.80, \$5.60 and \$7.50, respectively, plus an amount equal to all declared but unpaid dividends, respectively.

The total number of shares of which the Company is presently authorized to issue is Forty Million (40.000,000). Twenty-eight million (28,000,000) shares shall be Common Stock, and twelve million (12,000,000) shall be Preferred Stock.

Outstanding	prior to	the O	ffering or	August	1 1994
Administra			1511115 01	LAMEUSE	1 7 7 7 7

CONSTRUCTOR OF TOT	to the Offering of August 1, 177	 _	
Common Stock		1,617,532 shares	\$ 382,000.0
Series A Preferred	Stock	1,332,000 shares	\$ 26,000.0
Series B Preferred	Stock	779,1095 shares	S 1.636.309.5
Series C Preferred	Stock	205,933 shares	\$ 577,000.0
Series D Preferred	I Stock	1.589.196 shares Ch	S 8.899.498.0 53 1 17 17 17 17 18 18 18 18 18 18 18 18 18 18 18 18 18
Total Pre	-Offering Shares Outstanding	5,523,856 shares	\$11.520.807.5
		15,3,5%	-11.7.13

Dividend Policy

The Company has not paid any dividends since its inception and does not intend to pay any dividends in the foreseeable future.

SELECTED FINANCIAL DATA

The selected financial data below has been derived from annual financial statements, including the audited balance sheets at January 31, 1994, and 1993 and the related statements of operations and of cash flows for the years then ended, for the period from June 19, 1991 through January 31, 1992, and notes thereto appearing elsewhere in this Prospectus. The selected financial data for the six months ended July 31, 1994 have been derived from unaudited financial statements; however, in the opinion of management, such data includes all adjustments, consisting only of normal recurring adjustments, necessary for a fair presentation of such data. Results for the five months ended June 30, 1994 are not indicative of results that are expected for the full year.

MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

Overview

The Company is a development stage company with limited sales of its first product line, the SafeSnap safety syringe. From its inception in 1991 through June 30, 1994 the Company has incurred ongoing losses from operations. As of June 30, 1994 the Company had cumulative net losses totalling \$7,060,600. Since its inception, the Company's principal focus has been the design, development, testing and evaluation of its safety syringe products and the design and development of its molds, assembly machines and production processes.

The Company expects to sell 29 million units of its SafeSnap syringes, achieving revenues of \$7 million, by fiscal year ended January 31, 1995, based upon the current assembly capacity of its subcontractors, Nypro Precision Assemblies and Kendall Healthcare, along with the soon-to-be-implemented of high-speed assembly automation. The Marketing and Sales department has already received either written or verbal purchase commitments for large percent of those 29 million wits, through its recently established Master Dealer Network of distributors. (See Sales and Marketing Section of the August 1994 Business Plan herein).

Five Months Ended June 30, 1994

Since February 1, 1994 the Company received \$3,862,000 from the sales of Series D Preferred Stock and \$458,000 from the exercise of options to purchase shares of Series B Preferred Stock through June 30, 1994. Approximately \$1,712,000 was disbursed during the five months ended June 30, 1994 for property and equipment, as reflected in the June 30, 1994 Balance Sheet.

Since February 1, 1994 the Company completed tenant improvements and relocation to the leased facility in Rancho Bernardo, California. In addition, the Company received the first full set of 3cc SafeSnap multi-cavity molds, 7 additional injection molding presses, as well as other auxilliary equipment. Furthermore, the facility has successfully passed all regulatory inspections, including that for compliance to the FDA's "Good Manufacturing Practices" standards.

Since February 1, 1994 the Company has solidified its management team by hiring distinguished and highly-experienced people for the positions of Senior Vice President of Sales & Marketing, Vice President of Engineering and Operations, Vice President of Quality Assurance/Regulatory Affairs, and Vice President of Finance and Administration.

Since February 1, 1994, the Company's sales and marketing department has successfully developed a Master Dealer Network consisting of 13 distributors whose combined territories cover all 50 U.S. states. Through these master dealers, several hospitals and alternate care facilities have already

U.S. Medical Instruments, Inc.
SERIES E PREFERRED PRIVATE PLACEMENT

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elected to convert to in SafeSnap syringe injection program, thus creating master dealer demand for at least one third (1/3) of the Company's production capacity over the next three years.

The Company had minimal revenues of \$3,000 for the five months ended June 30, 1994, primarily due to the Company's relocation, regulatory requirements and the implementation and validation of new machinery and equipment. The Cost of Goods Sold were \$397,500 for the past five months ended June 30, 1994, primarily reflecting raw material inventory as well as the increased labor and overhead related to the manufacturing and quality/regulatory affairs departments.

Engineering and research and development expenses were \$170,000 for the five months ended June 30, 1994. The Company's efforts in these departments focused upon refining the mold cavities of its 3cc SafeSnap syringe multi-cavity tools, the implementation of new machinery and equipment and upon the design and development of its 10cc and 1cc syringe designs and prototyping.

Selling and Marketing expenses were \$193,000 in the five months ended June 30, 1994. The increase in these expenses resulted primarily from an increase in sales and marketing and administrative personnel to support commercial sales, along with trade shows and marketing activities in preparation for a national sales launch in the second half of fiscal 1995.

General and Administrative expenses were \$601,400 in the five months ended July 31, 1994. Relative increases resulted primarily from the increases in finance and administrative personnel, rent, several non-recurring events, and expenses related to the implementation of manufacturing resource planning systems and other computer-related needs.

Interest expense was \$18,900 for the five months ended June 30, 1994, reflecting interest paid on various capital equipment leases.

Inventory value at June 30, 1994 consists principally of purchased raw material costs or work-in-process. Certain purchased components have lead times of several months.

Net Income in the five months ended June 30, 1994 was (\$1,378,000), increasing the Accumulated Deficit to (\$7,060,600).

Year Ended January 31, 1994 and January 31, 1993

The Company had revenues of \$1,000 for the year ended January 31, 1994 and revenues of \$5,000 for the year ended January 31, 1993, derived from samples purchased for evaluation of the SafeSnap syringe during the development stages of the Company.

The Company incurred research and development expenses of \$1.1 million and manufacturing and start-up costs of \$626,000, as compared to \$249,000 and \$366,000, respectively in fiscal 1993. Those increased costs between fiscal 1994 and 1993 reflect the growth of the employee base, the completion of start-up costs for the 6cc syringe, and the design, development, prototyping and start-up costs related to manufacturing of the 3cc syringe design.

General and administrative expenses were \$1.05 million in fiscal 1994 as compered to \$651,000 for the year ended January 31, 1993. The increase in costs resulted primarily from the hiring of additional personnel, and several non-recurring events.

Selling and marketing expenses were \$385,000 in the year ended January 31, 1994 compared with \$571,000 in the year ended January 31, 1993. The Master Distributer Network strategy implemented during fiscal 1994 yielded lower costs of sales to the Company, while incentivizing the distributors with higher margins.

Interest expense was \$67,000 for the fiscal year ended January 31, 1994 compared with \$8,000 for the year ended January 31, 1993. Much of that increase is related to payments on a loan of \$900,000 to a shareholder, to finance the first set of 3cc multi-cavitation moids. See "Certain Transactions."

During fiscal 1994, the Company received funds in the amount of \$2,566 million from the sale of common and preferred stock and \$100,000 from the issuance of warrants and options. In fiscal 1993 the Company received funds of \$3,247 million from the sale of stock. In fiscal 1994 and 1993, respectively the Company made payments of \$1.624 million and \$1.025 million on property and equipment. The remainder of funds raised was applied toward various working capital requirements.

The Company's total assets increased from \$1.825 million in fiscal 1993 to \$2.791 million in fiscal 1994, primarily related to the increase in property and equipment. Total liabilities increased from \$240,000 in fiscal 1993 to \$1,765,000 due primarily to the borrowing of \$900,000 for the 3cc molds.

Commitments and Contingency. Lease agreement and purchase orders on Machinery & Equipment (See audited financials notes). In October 1993, the Company and McDonnell Douglas Corporation agreed to a lease arrangement in the amount of \$1,030,000 for the 52,000 square foot facility located at 16825 Via del Camp Court, Rancho Bernardo CA. The lease term is sixty months from January 1, 1994.

During the year ended January 31, 1993, the Company paid \$250,000, respectively to acquire the exclusive long term license to certain patents, technical data and trade styles relating to its safety syringe. During fiscal 1994 the Company paid \$50,000 as a minimum royalty fee to the licensor related to this agreement. The license agreement requires the Company to pay minimum royalties of \$125,000 and \$175,000 in fiscal 1995 and 1996, respectively. The license agreement may be termilated by either party.

In February 1993, the Company underwent a five-for-one stock split recapitalization plan, whereby four new series of preferred shares were created, and allocated to shareholders based upon the purchase price and timing of their investment. Certain rights, privileges and preferences related to the liquidity of the Company were defined based upon the Series of Preferred. See "Capitalization" Section.

Liquidity and Capital Resources

The Company's need for funds has increased from time to time as it has increased its research and development activities, expanded staff and commenced the purchase of molds and production equipment. To date the Company has financed its operations principally through private placements of equity securities. As of July 31, 1994, the Company had received net proceeds of approximately \$11,500,000 through the sale of equity securities.

The Company's cash and short-term investments at June 30, 1994 will be used primarily for working capital and payments due on certain machinery.

The Company's working capital and other capital requirements during the next year or more will vary based upon a number of factors, including the rate at which production capacity is expanded, the level of sales and marketing activities for the SafeSnap syringe, and the level of effort needed to develop the Icc and 10cc SafeSnap syringes to the point of commercial viability. The Company believes that the funds described above, together with the net proceeds of the Offering and funds generated from the sale of currently available products, will be sufficient to support the Company's operations and planted capital expenditures through at least June 30, 1995. The Company's failure either to produce sufficient quantities of safety syringes or to manufacture the safety syringes at or near the estimated cost per unit could materially and adversely affect the Company's cash flows. In addition, the Company's business plans may change or unforeseen events may occur which require the Company to raise additional funds.

U.S. Medical Instruments, Inc. AUGUST 1994 BUSINESS PLAN

A. General

U.S. Medical Instruments, Inc., ("U.S. Medical" or the "Company"), is a technology-based medical device manufacturer with the mission of developing, manufacturing and marketing safety-enhanced medical instruments that are both cost-effective and user-friendly. The California corporation's first product is SafeSnapTM, a patented line of single-use hypodermic syringes that will substantially reduce the incidence of accidental needle sticks in the healthcare and homecare markets. The technically and aesthetically superior high-precision SafeSnap design is unlike any other syringe available on the market, in that it permits the used needle to retract into the syringe barrel, completely shielding the needle from human contact.

Management intends to capture at least five percent of the more than 5 billion unit annual U.S. syringe market over the next five years, and use the resulting income and manufacturing capabilities as a platform for launching other safety-enhanced medical devices. These follow-on products include safety winged-butterfly catheters, vial adapters, safety arteriovenous fistula needles, and blood-gas syringes, currently in their early stages of development. Revenue from the core SafeSnap business alone is projected to reach S48 million by the fiscal year ended January 31, 1997, with gross margins in excess of 50%.

B. The Syringe Market

In the healthcare community, the syringe represents the single largest segment of medical instrumentation calculated in terms of units used. There has been no significant design change other than the switch from glass to plastic, which occurred more than 25 years ago, within the syringe industry. In third world countries the use of glass syringes and the re-use of syringes is still prevalent. Syringes are used for introducing drugs into the body and drawing out blood and other bodily fluids. Syringes are found in hospitals, laboratories, clinics, doctors' offices and homes. Among the primary applications for syringes are the injection of drugs and vaccines, and the infusion of drugs and nutrients. There are approximately 6,500 hospitals located in the United States.

Currently, more than 16 billion disposable syringes are sold each year world wide. The U.S. market accounted for an estimated 4.6 billion units, where approximately 3.5 syringes are consumed daily per hospital bed. It is estimated that safety syringes currently represent approximately 15% of U.S. syringe sales, but are expected to grow at a faster rate than the domestic syringe market as a whole, as better designs and larger volumes are made available. According to Theta Corporation's January 1994 Report #346 Medical Needles and Syringes, "Demand (for all syringes) is projected to increase each year through 1995 as health care facilities make the switch to safety syringes, driving up hospital inventories and manufacturers' sales during the transition period. When market penetration for safety products reaches approximately 75% in 1996, growth will fall to sustainable levels reflecting the underlying growth factors of demographic increases in patient populations and changes in injectable treatment therapies. These factors include an increasing number of elderly Americans, growing use of multiple-injection insulin regimens for diabetics, and growing availability of biotechnology drugs, which typically require parenteral administration. The compound annual growth rate [for all syringes] from 1993 to 1998 [in the U.S.] is projected at 5.3 percent (Theta Report, page 15). The estimated domestic market size for syringes is thus approximately 6 billion units in 1998.

Significant consolidation within the syringe manufacturing industry has occurred during the past two decades. Baxter international, Johnson & Johnson, Abbott Laboratories, and Smith Kline Beecham have all exited the syringe manufacturing industry. Becton-Dickinson ("B-D") and Sherwood Medical

Lo Why?

("Sherwood", an American Home Products Subsidiary) are the only remaining major domestic competitors, with the Japanese company Terumo trailing far behind. B-D, with approximately 70% of market revenues for needles and syringes, together with Sherwood, with approximately 10 percent of market revenues dominate the \$534 million U.S. syringe market. (Theta Corporation, page 14)

· Manufacturers' Market Share
Total Needles & Syringes, 1992

Company	Revenues	Market Share (%)
Becton Dickinson	\$379,800,000	71%
Sherwood Medical	\$ 58,800,000	1196
Terumo Medical	\$ 37,400,000	7%
Others	\$ 58,800,000	11%
TOTAL	\$534,900,000	100%

Due to the various market segments that purchase syringes, including hospitals, alternate care, and physician offices, as well as due to the various sizes demanded by different segments, syringe pricing is quite volatile. On average, 3cc syringes may sell to hospitals for approximately 10 cents unit, while they would sell to an alternate care or physician facility for as much as 20 cents/unit. The generic syringe market is viewed frequently as a commodity market that is price elastic. To the competitive syringe manufacturing companies, the hypodermic syringe is a "cash cow" anchor product, which facilitates their selling peripheral and additional medical devices to the same customer.

C. Accidental Needlesticks/Regulatory Response

World-wide concern about the spread of contagious blood borne chronic diseases (see Appendix) is reaching a point rivaling that of raging smallpox or polio epidemics. This is especially true of viruses such as Hepatitis B and HIV, which are transmissable through some exchange of body fluids, and are difficult or impossible to counteract with currently-available treatments. Whole blood, blood plasma, cellular components of blood, tears, semen, or products which are derived from any of these are all centers of focus and concern.

Despite extensive training procedures and growing awareness, 80% of reported accidental needlesticks occur after injection of a patient (see Exhibit A). As of September, 1992 there have been at least 36 reported cases in the U.S. in which healthcare professionals have become infected with the AIDS virus through accidental needle sticks (see Appendix B). In addition, the Center for Disease Control estimates that more than 12,000 individuals contract Hepatitis B each year through needlesticks, and 250 healthcare personnel die of Hepatitis contracted from patients each year.

NOSOCOMIAL INFECTIONS TRANSMITTED BY NEEDLESTICKS

AIDS
Hepatitis B
Syphilis
Malaria
Tuberculosis
Staphylococcus aureus
Streptococcus pyogenes

Hospitals are being pressured to introduce safer medical instruments and sharps devices by employees, proposed local ordinances, state and federal legislation, and the increasing number of lawsuits brought against hospitals by medical personnel and patients who are victims of needle-stick-related infections. One recent lawsuit whereby a nurse sued NewYork State after contracting HIV from an accidental needle-stick resulted in an award in excess of \$5.4 million (see Article in Appendix C). The Hospital Employee Health ("HEH") newsletter estimates that the costs of each reported accidental

Case 3:96-cv-01187-J-CGA Document 16 Filed 10/28/96 Page 93 of 212 needlestick are appropriately \$1,200 for treatment of the wound, diagrant tests and lost worker time, exclusive of specialized, longer term treatment and potential liability costs.

The Occupational Safety and Health Administration ("OSHA") has adopted regulations requiring thealthcare institutions to institute universal precautions to prevent contact with blood and other potentially infectious materials. OSHA has also adopted regulations requiring healthcare institutions to establish engineering and work practice controls to insure compliance with these universal precautions. As a result of these controls healthcare institutions utilize equipment, including safety syringes, and work practices that offer greater protection for healthcare workers than previously provided.

Recently in deliberation, California Congressman Pete Stark introduced Anti-Needle stick Legislation, H.R. 1304, which is designed to place an excise tax on non-safety needles beginning in 1997. (see Appendix). This legislation aims to pressure hospitals to use needles with built-in safety protection, while providing manufacturers with the economic incentive to improve the designs of sharps devices. Rep. Stark introduced this legislation following the death of 29-year-old Kaiser nurse Melissa Campbell, who contracted AIDS from a needle stick. "This is to provide the price encouragement for the right thing - to provide a safer working environment for our nation's caregivers.", announced Rep. Stark.

Congressman Stark's testimonial on June 29,1993 before the Committee On Ways and Means states: "Over 800,000 needlesticks occur each year. At a cost of \$600 for testing and counseling for each stick, the financial burden is tremendous. The psychological toll is even greater". Furthermore, Rep. Stark's testimony did not mention the exhorbitant price invovled or the potential legal liability when medical treatment such as AST (for HIV) is required. In a previous testimonial he gave on March 10, 1993 Rep. Stark comments that "the estimated average cost of treating just one person with AIDS is \$102,000 while the cost of converting an average 300 bed hospital to a safer device is only \$31,000."

As of January 1, 1992 the California Department of Health Services/California Occupational Safety and Health Association (Cal OSHA) has enforced bill AB18-70, authorizing all hospital occupational health departments to develop a program to track the effectiveness of safety devices, and to contribute toward the development of standard guidelines for sharps. Similar laws are being passed throughout the country. These laws will promote widespread awareness of the frequency and risks of needle sticks and create public and internal pressures within the healthcare industry to purchase the safest medical devices available.

On December 6, 1991, the Federal Occupational Safety and Health Administration issued 29 CFR Part 1910.1030 -Occupational Exposure to Blood borne Pathogens; Final Rule, emphasizing that the strictest caution be used when handling needles and syringes.

As a result of all these pressures and the recognition of the dangers posed by syringes, the marketplace is demanding an answer to the ever-present risk of needle-stick injuries at a cost-benefit ratio that can be widely acceptable. The World Health Organization ("WHO") recently stated: "The least expensive competitive disposable syringe available has major shortcomings. It is too expensive, too fragile to be sterilized, and is frequently not disposed of at all, but re-used many times". According to the WHO, the syringe design required in the healthcare environment should:

- Passively auto-destruct, i.e., require no effort from the operator;
- Be simple to manufacture, transport, and use.
- Be similar enough to the existing reusable syringes to avoid the need for lengthy
 evaluation of its safety.

They also state: "The economic stakes for {syringe manufacturing} companies are high. The estimated annual demand throughout the world for an auto-destructible syringe for all purposes is in the billions - 7 billion could be needed in Europe and the United States alone."

Thus, safety, quality, cost-competiveness and user-friendly features are significant concerns when evaluating the feasibility of the ideal safety syringe. The SafeSnap syringe best satisfies the World Health Organization's criteria. Furthermore, SafeSnap is cost competitive with generic, non-protective syringes, but can take advantage of the established premium pricing.

D. The Safety Syringe Market

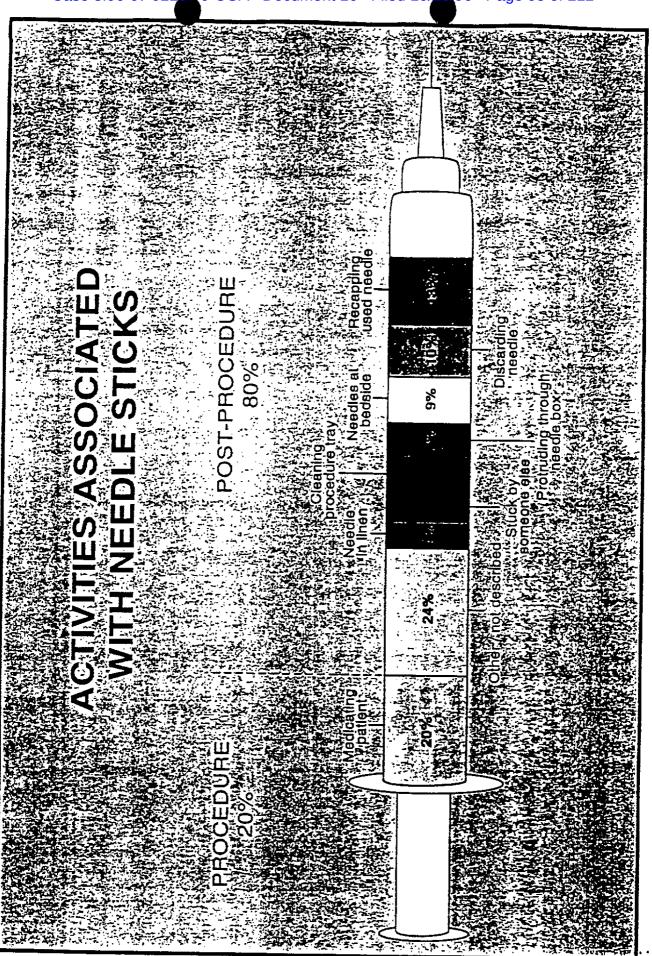
Safety syringes today comprise approximately 15 percent of the syringe market, or about 894 million units. This 15 percent is primarily manufactured by B-D and Sherwood, who, over the past three to four years, have each introduced a needle-shield, or :"sheath", approach to the safety syringe market. While the performance and safety of these two syringes is questionable, as discussed below. B-D and Sherwood's marketing efforts for these products have created market acceptance of premium pricing for safety syringes. Safety syringes, for now, are not viewed solely as commodity items.

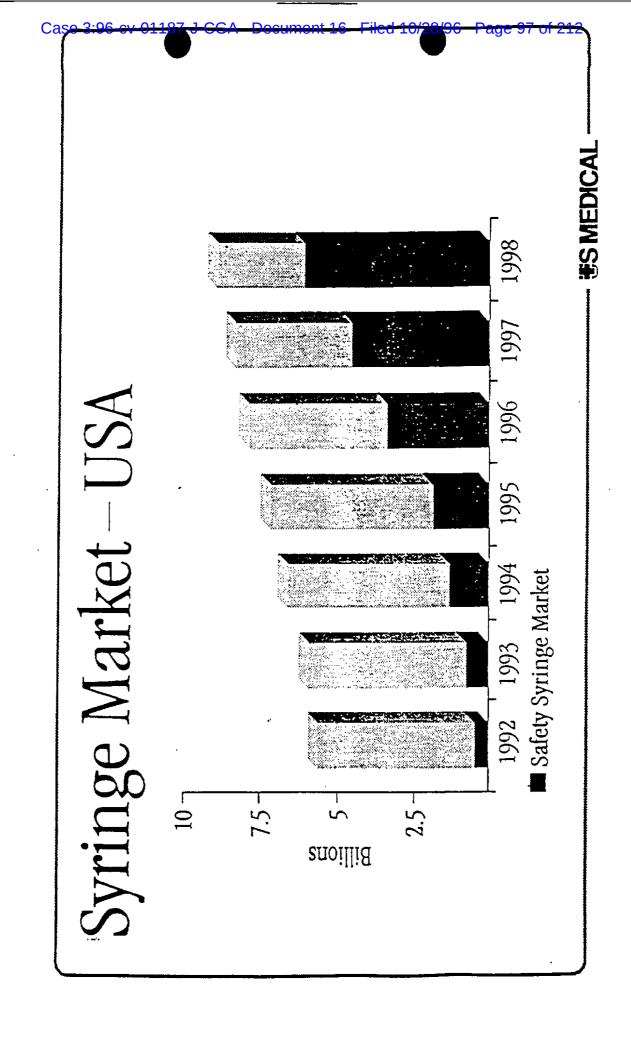
According to the recent study released by Theta Corporation (January, 1994), safety syringes will rapidly penetrate the syringe market during the next 5 years, capturing up to 80% of the syringe market by 1998, or approximately 4.1 billion units. This represents a compounded annual growth rate of more than 35% from 1993 to 1998.

Both B-D's and Sherwood's safety syringes provide an external sliding sheath over their basic syringe, that can be extended over the needle after use. These devices have several shortcomings: the plastic sheath is an expensive addition to the manufacturing cost of the basic syringe; the device does not destruct, and is therefore reusable; nurses complain that the sliding sheath of both B-D and Sherwood's safety syringes is cumbersome, citing that when the sheath slides forward, it obstructs the administration of the drug; the sheath approach creates a false sense of security and has actually been the muse of some needle stick occurrences. As recent as June, 1993, B-D had a Product Recall on its 3cc safety syringes, due to a defective locking mechanism. B-D and Sherwood safety syringes are currently being sold at premiums of three to five times that of non-safety syringes.

Syringe Market Characteristics Summary:

- Demand for safety syringes is being pushed by Regulators, Lawmakers, Nursing Unions, Clinicians, High Cost of Liability, and desire to remain competitive with other reputable organizations.
- The safety syringe is accepted as a premium-priced item over nonprotective syringes.
- * The annual demand for total number of syringes is rising domestically and worldwide, exceeding 4.8 billion and 16 billion units, respectively. In addition, associated market growth is expected to exceed 5% and 15% per year, respectively.
- * Safety syringes today represent approximately 15 percent of the U.S. syringe market, but have the potential to take as much as 80% of the market in the next five years. Hospitals increased their purchasing of safety needles/syringes by 59 percent over the past year, according to "Materials Purchasing News", June 1993 issue. (See Appendix C)
- * The larger manufacturers recognize the long term need to overhaul their generic syringe business into the safety syringe business, but are not attempting to pave the road themselves and risk their "cash cow" businesses until absolutely necessary.





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E. The Product

U.S. Medical Instruments, Inc.'s SafeSnap syringe is the best safety syringe alternative for the healthcare market, from quality and safety to user-friendliness. The patented SafeSnap design has been developed over the past four years. Its unique features, technically and aesthetically, are a direct result of constructive criticism received by industry experts, doctors, nurses and other healthcare professionals

The Medical Device Amendment Act of 1976 establishes three designations for regulated devices: Class 1 (general controls), Class II (standards), or Class-III (pre-market approval). The SafeSnap syringe is a Class II device. As such, the company receives "premarket approval" from the U.S. FDA under Section 510(k). U.S. Medical received such approval on April 16, 1991.

SafeSnap is comprised of six components:

* Barrel * Plunger Rod

Needle Carrier • Translucent O Ring

Black Two-Lobed Stopper * C Clip

The high precision specifications incorporated in the SafeSnap syringe components permits the used needle to retract into the syringe barrel, completely shielding the needle from human contact. While the design is highly precise, the amounts of material utilized are similar to non-protective syringes; therefore the cost to manufacture these parts in automated volume is only fractions of a penny more than the cost of generic syringe designs.

The SafeSnap design has several original and unique features:

- * The needle carrier is a separate piece within the barrel, with a clear silicone o-ring, and a luer lock mechanism. Whereas in an ordinary syringe the needle attaches to the barrel, the needle attaches to SafeSnap's needle carrier.
- * The standard luer lock feature allows the users to use their needle-of-choice with the SafeSnap syringe.
- * The plunger rod engages the needle carrier when the injection of medication is spent by the clinician.
- * Once the carrier is engaged with the plunger, a simple flip of the red safety clip allows the needle carrier to be pulled back into the barrel. The c-clip also preverts the plunger rod from prematurely retracting the needle if the user does not unhinge the c clip
- * The plunger is designed such that once the needle is retracted into the barrel, the plunger is easily broken off at its perforated cross section. This renders the syringe non-reusable.
- * The broken portion of the plunger is designed to be inserted into the front end of the barrel, snapping into place. This renders the needle completely encapsulated within the barrel
- The plunger rod and barrel are designed so that the plunger rod cannot be pulled out of the barrel using ordinary pressure.

The SafeSnap syringe is sold with or without needle. Several needle sizes are avzilable, and the product is packaged utilizing a color-coating identification that is comparable to other standard hypodermic needles.

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At present the 3cc and 5cc SafeSnap syringe sizes are available for sale. These two sizes account for approximately 60 percent of the hypodermic syringe market. Currently in their design and prototyping stages are the 1cc and 10cc SafeSnap sizes, completing the line of syringes most commonly used for patient injections.

SafeSnap provides the following features and benefits to its customers:

SafeSnap Features and Benefits to Users/Customers

<u>Maximum Security:</u> The design of the SafeSnap Syringe, which permits the used needle to retract into the barrel of the syringe completely shielding it from human contact and preventing reuse provides a level of safety never before available.

Cost Effective: The reduction of needle stick injuries greatly reduces the cost of providing healthcare services. This is achieved by the reduction or elimination of medical testing, treatment, counseling, and employee down time, as well as potential legal costs. Studies have shown that the average costs for testing and counseling needle stick victims are as high as \$600 per incident, exclusive of the cost of medical treatment required if an infection is diagnosed.

<u>User Friendly:</u> Allows nurses to utilize standard technique in giving injections thus minimizing the need for extensive in-service education.

Medical Waste Protection: Reduces liability in the work environment as well as during the transportation to the final disposal destination. Also, reduces potential hazards in the event of improper disposal.

Single Use: SafeSnap is not reusable, and thus satisfies the requirements set forth by organizations such as the CDC. WHO and OSHA that competitive safety "sheath" devices do not. Sheath safety syringes presently for sale can be utilized again with the removal of the sheath.

Product Cost: SafeSnap syringes can be sold at prices comparable or lower than other safety syringes.

Full Product Line: Line will include several calibration sizes of syringes, permitting full conversions and purchasing syringes from one manufacturer.

Color Coded Packaging: Quick product identification saves time, allowing universal recognition.

Luer Lock Needle Holder: Permits user to employ needle brand and needle size of choice.

F. Patents

U.S. Medical owns the exclusive right to make, use and sell the proprietary property of several patents issued or pending covering the SafeSnap design and all designs associated with the development of this product. The patented design was developed by and is filed under the name of Matthew S. Mazur, the Company's Founder, and Carlos Manjarrez, the Company's Vice President, New Products, Research & Development. The first two patents of the several filed were assigned U.S. Nos. 5,205,824 and 5,308,329, and were issued in April, 1993 and May, 1994, respectively.

U.S. Medical's patent position is further strengthened with the exclusive licensing of certain key patents. The combination of these issued patents, in addition to the Company's patents still pending, represent a significant competitive barrier in the retractable safety syringe industry. U.S. Medical has also taken the necessary steps to file international patent rights in numerous countries.

G. Competition

While there are several companies attempting to develop devices or vying for a portion of the safety syringe/needle market, U.S. Medical considers its principal competition to be Becton-Dickinson and Sherwood Medical. In addition there are a number of other companies which offer safety needle devices. However, SafeSnap has a unique combination of benefits and advantages over all of these competitive product offerings.

Currently, the most recognized and common product design concept being marketed in the safety syringe market segment is to sheath the needle after use in order to make it difficult to suffer inadvertent injury. This concept has many shortcomings, including higher costs to the customer, re-use capabilities, non-user friendly designs which require radical technique changes, and non-conformance to the aesthetics of common syringe design. Below is a list of the primary and secondary competitor companies and their safety products.

Becton-Dickinson (B-D), the market leader in worldwide generic syringe sales, introduced a needle-shield syringe in 1988, named Safety-Lok. The syringe has an external sliding sheath that can be extended over the needle after use. Although the device is functional, the extra plastic used for the sheath is an expensive addition to the cost of the syringe. User acceptance of Safety-Lok has been poor due to its churnsiness and relative ineffectiveness at successfully preventing accidental needle sticks.

Sherwood Medical manufactures and sells the Monoject Safety Syringe which incorporates the same sheath principle as B-D's Safety-Lok but claims that its sheath will withstand higher pressures than that of the B-D Safety-Lok.

<u>Critikon</u>, a division of Johnson and Johnson and <u>Ryan Medical</u>, recently acquired by Winfield Industries, both followed B-D's lead by adopting a similar needle shield design for a protective catheter, distributed by Critikon, and a protective blood collection device that is produced and distributed by Ryan Medical. Those products have faced similar criticism as B-D and have had difficulty gaining market acceptance.

<u>LMP Enterprises</u> manufactures a snap-on version of the sheath that is universal for 3cc and 6cc syringes. Besides requiring an incremental cost, the sheath does not completely enclose the needle or render it non-reusable, and requires clinicians to make significant changes to their injection technique.

<u>Needle-Point Guard. Inc.</u> also manufactures a snap-on sheath sold separately from the syringe. This design has similar features and shortcomings as the LMP Enterprises design.

MedTech Group is a contract manufacturer in New Jersey. They manufacture their own proprietary line of retractable safety syringes that have a needle co-molded into the tip. This device cannot use standard needles and demands that the clinician twist the plunger rod to engage the needle carrier.

<u>SafetyJect International</u> is located in Vancouver, B.C., Canada. SafetyJect licenses needle products including the CareGuard intravenous connector with a recessed needle, and a butterfly scalp vein set for short-term intravenous therapy. SafetyJect is actively pursuing licensing arrangements to facilitate manufacturing, but are not presently in commercial distribution.

BioPlexus, Inc. is a 7 year-old development stage company based in Tolland, Connecticut, which has recently raised capital through the public markets to develop, manufacture and sell its "Punctur-Guard" blood collection needle. This needle is made with an extra sheath-like component within the cannula, such that once an injection is given, the sheath moves upward to round out the sharp edges of the needle.

Sterimatic Medical Corp. of New York City is the U.S. sales and marketing division of the U.K.-based Sterimatic Medical Systems Ltd. Sterimatic has developed a safety needle, the Sterimatic Safety Needle,

whereby the needle is set within a spring-loaded retractable sleeve. Another similarly-functioning safety needle, named The Protector, is being made by <u>InjectiMed. Inc.</u> of Ventura, California. Compared with a generic needle which sells for \$0.05 on average, Sterimatic and InjectiMed intend to sell their needles at per unit prices of \$0.60 and in excess of \$1.00, respectively.

U.S. Medical Instruments, Inc. has many advantages over its primary and secondary competitors:

U.S. Medical's Competitive Advantages

- Market Leader & Innovator: SafeSnap is the first and only retractable singleuse syringe in the healthcare market today.
- Patents: SafeSnap has strong patent coverage, domestically and internationally. Strengthened with the exclusive license agreement with Habley Medical Technology.
- * Maximum Security: Unlike most of the competitors, the SafeSnap design prevents re-use of the syringe, and provides complete encapsulation of the contaminated needle.
- * Product Development Time & Cost: Time requirements to design and build prototypes, as well as the high expense and lead time required to build multi-cavity molds, are significant barriers to entry. U.S. Medical has surpassed these as well as the many regulatory approval hurdles.
- * Long Term Staying Power: SafeSnap can be manufactured at costs similar to generic syringes, and thus can be more flexible and price competitive in the marketplace with safety and non-protective syringes.

H. Company Strategy

The Company's objective is to establish itself as a leading provider of safety syringes and related medical devices. To achieve this objective, the Company's growth strategy is focused on the following three principal elements.

- * Capturing significant market share of the syringe/safety syringe market
- Continued timely expansion of production capacity to facilitate demand.
- Developing and introducing new safety-related sharps product lines to penetrate closely related markets (safety winged-butterfly catheters, vial adapters, safety arteriovenous fistula needles, and blood-gas syringes)
- Seeking additional market opportunities based on the Company's proprietary technology (international licensing arrangements, private label manufacturing, packaging in medical kits, etc.)

I. Sales, Marketing & Distribution

The competitive advantages of SafeSnap can be exploited in several ways, each of which is being examined by Management and prioritized based upon the Company's future production capacity. Each strategy is not mutually exclusive. First to be implemented, SafeSnap will be sold and distributed under its own name, whereby U.S. Medical would build its own direct sales interface and distribution channels and or form alliances with distributors. Secondly, U.S. Medical is considering private label packaging for SafeSnap, as an Original Equipment Manufacturer (OEM) for other healthcare companies, who would then sell and distribute the product as their own safety syringe. U.S. Medical is also considering arrangements to package SafeSnap in medical kits with other products. Additionally, U.S. Medical is considering granting licenses to companies abroad that would manufacture SafeSnap for international markets.

The major U.S. healthcare market segments in which syringes are sold are:

U.S. Health Care Market Segments

- ' Hospitals
- Physician Offices
- * Alternate Site Market, including:
- Home Care Companies
 - Outpatient Clinics
 - SurgiCenters
 - Paramedic/Ambulance Services
 - Nursing Homes

Each of these segments has different purchasing habits, syringe size requirements and distribution channels. While some distribution organizations have the expertise and focus to access distribution of product into more than one of the above market segments, it is more typical that distribution organizations have a primary focus to a specific market segment.

Market research suggests that the syringe purchasing habits of hospital purchasers include the following:

HOSPITAL PURCHASERS

- Pricing is an important part of the decision making process
- Syringes are mostly purchased through negotiation with large purchasing groups for better prices with manufacturers due to volume
- Syringe purchasing is bundled with purchasing of needles and other medical devices
- Volumes are highly volatile by hospital, depending on the specialties and patient demographics
- Just-in-time inventory is growing more popular

Safety syringe purchasing habits are not as clear, since this is a developing market. However, independent market research conducted recently suggests that pricing, while still a concern, is not as sensitive towards safety syringes, and that purchasers already expect to pay premiums for safety syringes. Since many of the hospitals are not convinced that the safety syringes they have seen are the solution to needle-sticks, many are purchasing safety syringes, making them available to users, but not requiring their use. Management has reason to believe that as SafeSnap becomes available in larger quantities, hospitals will have more confidence in SafeSnap as a generic syringe substitute than they do in currently available safety syringes.

Market research suggests that healthcare workers using syringes have the following habits:

NURSES AND HEALTHCARE WORKERS

- Users prefer certain product packaging, calibration clarity, sharpness of needles.
- Users are concerned with quickness and ease of use and protocol.
- Users do not always follow correct disposal protocol, often recapping the needle.
- Users do not always wear gloves when giving injections, claiming that it prevents being able to feel the injection.

With regard to safety syringes, market research suggests that nurses that have experienced a needle-stick or know someone that has been stuck and exposed to infections are much more receptive to trying new, safer devices. Often these individuals become product champions for safety devices. U.S. Medical's experience to date is that when product is evaluated in a single hospital department, news spreads quickly and demand to evaluate SafeSnap on different units becomes a an intra-hospital issue. The vast majority of nurses that have evaluated SafeSnap prefer it over the safety syringes marketed by Becton-Dickinson and Sherwood Medical.

Management forecasts that the company's annual production capacity at the end of fiscal year 1997 will be 360 million units. The Company is presently exploring several private OEM arrangements, and is discussing exclusive arrangements with large syringe distributors.

DISTRIBUTION

U.5. Medical's products will be distributed by a network of Master Dealers (MD's) with geographic and market segmentation clearly defined (See Appendix B). U.S. Medical has recently formed alliances with 12 medical device master distributors, whose combined territories cover all 50 of the American states. These veteran organizations, comprising nearly 250 specialty medical sales representatives, have primary sales responsibility for Acute Care/Subacute Care facilities (hospitals and major clinics). They are also permitted to arrange for access to Alternate Site customers (doctors' offices, home care, long-term care, nursing homes, etc.) either through their own channels or by U.S. Medical-authorized arrangements with national vendors such as Owens and Minor, Stuart, Baxter, and General Medical. Additional providers may include regional dealers such as Foster Medical, PSS, F.D. Titus, et. al.

All of the Master Dealers are well-funded, highly successful, professional organizations with long and profitable prior associations with U.S. Medical business principals. Not only are they perfectly situated to present the safety syringes which constitute U.S. Medical's core business, but their call patterns will also make them strategically prepared to introduce each class of U.S. Medical's intended new product offerings.

CONTRACT MARKETING

It is the company's intention to continue exploration of large volume, exclusive or semi-exclusive private label arrangements with major providers of intravenous therapy.

The territoriality of the IV-fluid and pump business within the hospital and home care markets will provide large-scale entree via partnering with companies like McGaw, Abbott, Baxin, or National Medical Care. Ideally, the addition of a proprietary, premium-feature safety syringe will enhance the saleability of the partners' programs.

Early discussions have already begun with the "drivers" of these market segments.

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NATIONAL ACCUATE

Despite the dominance of the market's two majority players. Becton Dickinson and Sherwood, in the arena of Group Purchasing there appears to be a continuing opportunity for feature-oriented penetration. "Grass roots" clinical preference has been productive in the ultimate capture of small (yet significant) market share dollars at the headquarters level.

U.S. Medical intends to establish SafeSnap as the alternative choice to the "big two," predicated upon true clinical preference and upon demonstrable benefits, thus eliciting premium price acceptance.

Experience with both the Becton Dickinson and Sherwood safety devices has indicated that a real marketing opportunity exists among the "disappointed users" group. Too often, the promise of improved needlestick avoidance has apparently resulted in flat, or even negative, statistical benefits.

U.S. Medical is confident that a carefully crafted program, operated via a well-established national contract interface, can prove extremely rewarding. This project will be undertaken during fiscal 1995 for planning and strategic purposes. Implementation will occur early in fiscal 1996, when larger quantities of product begin to be available.

STRATEGIC CONSIDERATIONS

The Company has planned to initially target selected segments of the total audience for its earliest activity, in order to best position SafeSnap for national market exposure beginning in late fiscal 1995. These segments include homecare, hospital emergency departments, immunization clinics, specialty tray and kit suppliers, paramedic programs, etc.

The common denominator in these first segments is low-to-intermediate volume requirements coupled with the ability to pay requisite premium prices for demonstrably superior devices. As production accelerates with the addition of high speed automated assembly equipment, this foundation of early business will provide solid, credible documentation of both performance and price-point. The exponentially larger volumes necessary to satisfy the expanding customer universe will command lessening prices, but can nevertheless be expected to sustain some acceptance of the early premiums established with the specialty customer base.

SafeSnap will be established as the first (and only) <u>real</u> alternative to the "re-hashed" safety versions of old-style B-D and Sherwood devices. The intention of U.S. Medical's marketing staff is to create the perception of a <u>new class</u> of safety syringe: one that provides a completely new design concept with consistent, strong performance; not just a modified hybrid of a 25-year old design. The new positioning will cite SafeSnap as the first "Security Syringe", using the tag line "Minimum Risk, Maximum Security."

Beginning in fiscal 1995, U.S. Medical will launch SafeSnap on a national basis, concentrating on specific, clearly defined market segments. The Company intends to create a "big company mystique", while operating as a lean, guerrilla-style niche marketeer.

A wide variety of marketing activities will be utilized to support the efforts of the distributors and internal sales organization including:

U.S. Medical Marketing Activities

- Evaluations, conducted by independent third parties, to prove features and benefits.
- Working with influential decision makers and leading clinicians to obtain testimonials.
- * Customer education programs.
- * Trade-show displays including pre-meeting direct mail.
 - Brochures and related materials.
- * Direct mail campaigns.
- * Strategically-timed news releases and press kits.
- Journal Advertising Campaigns.

U.S. Medical intends to continue to take advantage of the premium pricing of safety syringes in the marketplace, but will be sensitive to price fluctuations in the safety syringe market.

J. Production

FACILITIES:

U.S. Medical manufactures the SafeSnap syringe line and conducts its marketing and product development activities at the Company's new facility located at 16825 Via del Campo Court. Rancho Bernardo Corporate Center, in Rancho Bernardo, California. This facility is licensed by the FDA in compliance with the guidelines set by the "Good Manufacturing Practices" requirements for medical device manufacturers.

U.S. Medical signed a 5 year lease with two (2) three year options for this production facility. The 5-year old 52,000 square foot building was built and is owned by the McDonnell Douglas Corporation, the St. Louis-based defense manufacturing company. The facility provides U.S. Medical with the space to expand production capacity up to monthly production capacity of 25 million units.

PRODUCTION PROCESS

The Rancho Bernardo facility represents a vertically integrated, top quality production process. Within the building is the Company's own mold-making tool and die shop, where its high-precision mold-making specialists design and build most U.S. Medical molds and prototypes. This in-house shop permits quick turn around for building and maintaining the molds.

High-precision stainless steel syringe molds are the core of the Company's production process. A well-designed, well-built mold will maximize raw material utilization, minimize the cycle time, hold to the strictest tolerances, and last for as long as fifteen years. The more cavitations in a mold, the greater the volume capacity per cycle. The company believes that the expense, time and proprietary technology required to build similar molds and create prototypes is a strong barrier to competition extering this market segment.

Almost all of the syringe components are purchased in raw form and injection molded to form the parts. This molding process is conducted at U.S. Medical's facility within its Class 100,000 controlled environment room. Once the parts are formed, they must be assembled and packaged. The packaged syringe is then boxed and cased. The cased product is shipped to a regional irradiation starilization facility for sterilization. Once quality control tests are performed to satisfaction, the product is released for distribution.



"I feel good about what I'm doing...
I just wish I didn't have to worry
every time I give an injection."

WITH SAFESNAP YOU CAN BREATHE EASIER. It's the first security springe specifically designed to protect

1) PUSH plunger, you against flip red clip. dangerous needlesticks. Only SafeSnap protects you from the moment of injection to the moment of disposal.

SafeSnap is also
the only security
syringe with a
retractable needle
that locks and
seals safely inside the
barrel. Where it can't
lunger stick you or anyone
needle, else. Ever again.

And unlike other

3) SEAL barrel with plunger.

so-called safety syringes, SafeSnap has no extra bulky parts. Which makes it easy to read. And even easier to handle in an emergency.

But best of all, SafeSnap can be disposed of simply and safely. The small sealed unit saves a lot of space in the sharps container, and won't add to the jumble of exposed needles. It's a double security system that works. Discover what it's like to feel safe again. For a free trial call 800-SAFESNAP (800-723-3762).

SafeSnap*

USMEDICAL.

D 1994 U.S. Medica, instruments, Inc



PRODUCTION CAPACITY:

U.S. Medical now has the production capacity to produce the molded parts for at least five million units per month. Until the already-on-order high-speed assembly automation equipment arrives in the fourth quarter of fiscal 1995 (the 1995 fiscal year is from 2/1/94 to 1/31/95), assembly operations will be conducted at the Nypro Precision Assemblies, Inc. and Kendall Healthcare Macqiladora facilities under subcontracting agreements. The implementation of high-speed assembly automation will permit the Company to immediately maximize the efficiency of the production process, as well as recognize cost savings associated with economies of scale.

The Company anticipates that additional sets of high-cavitational molds and high speed assembly and packaging automation will come on-line throughout fiscal 1996 and 1997 such that total production capacity will be 144 million units and 300 million units, respectively.

SHORT TERM PRODUCTION PLAN:

The short term production plan is to proceed on two tracks simultaneously. The first track currently in place is for U.S. Medical to continue its joint manufacturing agreements with its subcontractors, assembling and packaging SafeSnap syringes in their Maquiladora facilities using parts which are molded by U.S. Medical. Management has concluded that both companies' experienced manufacturing teams in FDA-approved medical facilities and located 3 miles south of the U.S. Border, provides U.S. Medical with healthier margins during the interim production stage, and assists U.S. Medical in absorbing future start-up costs. Working with Nypro's and Kendall's facilities in Mexico permit U.S. Medical to meet its fiscal 1995 objectives to sell 29 million units.

While production capacity for fiscal 1995 will be greater than this 29 million units. Management believes investing capital in high-speed automation equipment is the best investment for long term profitability. Thus, the other track being pursued is the design and acquisition of high-speed automated production equipment for the streamlined "hands-off" Rancho Bernardo facility. Fully-integrated high-speed production will permit the Company to recognize significantly better per unit costs due to efficiencies and economies of scale and the reduction in direct labor expense.

The second track being following is that during the next 12 months, Management will continue its plan to boost production capacity and round out the SafeSnap product line, by ordering and financing new sets of production molds and automation equipment for the 10cc and 1cc SafeSnap sizes. Investment capital is required to purchase the assembly equipment, packaging machines and other peripheral equipment. Financing for equipment such as the injection molding presses has been arranged by the vendor. The Company has been able to take advantage of recent tax breaks from State of California, receiving sales tax discounts on all new capital equipment received after January 1, 1994. Overall, the expansion requires additional equity in the amount of approximately \$8 million.

LONG TERM PRODUCTION PLAN:

Over the next three to five years, Management intends to purchase additional sets of production molds such that monthly production capacity will increase to 30 million units a month by the last quarter of fiscal 1997 and 50 million units a month by fiscal year 1999. As the Company ramps up production it forecasts the sale of 29 million units in fiscal 1995, 144 million units in fiscal 1996, 300 million units in fiscal 1997, 450 million units in fiscal 1998 and 600 million units in fiscal 1999. The total production capacity from fiscal 1997 onward accounts for the 1cc, 3cc, 5cc, 10cc, 20cc, 30cc and 50cc sizes and thus will comprise a well-rounded SafeSnap product line.

Additionally, but not included in this business plan's financial projections, the Company is presently working on the development of additional sharps safety product lines to complement the syringe line and increase the efficiency of marketing and sales efforts. See Section K.

K. Future Market Opportunities

U.S. Medical will seek to enter additional markets in situations where it believes that it can gain significant market share based on its technology or by capitalizing on its sales channels for complementary products. Within the field of needle related products the Company is developing new safety designs for devices including winged-butterfly catheters, arteriovenous fistula catheters, and blood-gas syringes. Another new product in the works is a medication vial adapter, which eliminates the use of needles when filling a syringe. The Company has commenced development of prototypes for several of these products. There can be no assurances that the Company will successfully design, manufacture and sell any such products.

L. Employees

As of June 30, 1994, the Company employed 39 people including 3 research and development employees, 22 manufacturing, quality and mold shop employees, 4 sales, marketing employees, 8 general and administrative /finance employees, and 6 mold shop employees. By December 31, 1995, the Company expects to significantly increase the number of employees, principally in the manufacturing department. The planned increase in personnel is based primarily on expected increases in production and sales of the SafeSnap syringe line. The Company's employees are not represented by a labor union and the Company believes its employee relations are good.

M. Legal Proceedings

The Company is not involved in any legal or administrative proceeding material to its business.

N. Environmental Matters

The Company believes its operations are currently in compliance in all material respects with applicable Federal, state, and local laws, rules, regulations and ordinances regarding the discharge of materials into the environment. Such compliance has no material impact upon the Company's capital expenditures, earnings or competitive position, and no capital expenditures for environmental control facilities are planned.

EXECUTIVE OFFICERS AND DIRECTORS

Name	Age	Position
James Yarter	58	Chairman of the Board of Directors
Matthew S. Mazur	30	Director, Chief Executive Officer,
		President
Carl Brown	69	Director, Corporate Secretary
George Schapiro	5 0	Director
Ronald Benincasa	52	Senior Vice President, Sales & Marketing
Scott Dolin	38	Vice President, Engineering &
		Operations
Sally Grigoriev	38	Vice President, Quality Assurance &
		Regulatory Affairs
Carlos Manjarrez	37	Vice President, New Products, Research
<u></u>		& Development
Charles Monts	39	Vice President, Finance & Administration
	•	***

BACKGROUND OF OFFICERS AND KEY EMPLOYEES

James R. Yarter

Mr. Yarter, Chairman of the Board of U.S. Medical, is currently the Chief Executive Officer of Block Medical, Inc., a San Diego-based medical device manufacturer of I.V. infusion therapy products. Previously, Mr. Yarter was the President and Chief Executive Officer of Pancretec Inc., which was acquired in a 1989 by Abbott Labs. Mr. Yarter is presently on the Board of Directors of Menlo Care, Curaflex Inc. and Block Medical Mr. Yarter has been a Director since the Company's inception in 1991.

Manhew S. Mazur

Chief Executive Officer, President and Founder of U.S. Medical Instruments, Inc. Over the past four years, Mr. Mazur has developed the SafeSnap proprietary product line and secured the necessary patent licenses needed to commercialize the product. Mr. Mazur provided a substantial amount of the initial seed capital for the Company (see "Shareholders"), and has been an instrumental force in the Company's fundraising activities. Prior to forming U.S. Medical, Mr. Mazur was employed at Foothill Capital Corporation, the asset-based lender subsidiary of The Foothill Group. Mr. Mazur is a graduate of Brown University.

Carl Brown

Mr. Brown is a senior partner with U.S. Medical's patent firm of Brown, Martin, Haller and McClain. Mr. Brown has been an advisor of the company since its inception. Mr. Brown was recently named one of California's top ten attorneys, and has performed the legal patent work for various Fortune 500 companies. Mr. Brown has been a Director since the Company's inception in 1991.

George A. Schapiro

Mr. Schapiro is a Director of 5 high-tech privately-held compenies, and was recently the interim President of Hepatix, Inc. For 16 years prior he was President of Andros Inc., a NASDAQ-listed manufacturer of gas analyzers. Mr. Schapiro's broad experience includes serving as CEO of Novacor Medical Products Corporation (later acquired by Baxter Healthcare International), initial public offerings, private financings, and post-IPO transactions. Prior to Andros, Mr. Schapiro was a Product Market Manager for Hewlett-Packard, responsible for the patient monitoring product line. He has been a member of the Young President's Organization since 1984 and is a Director of the Anesthesia Patient Safety Foundation. Mr. Schapiro has been a member of U.S. Medical's Board since December, 1992.

Ronald Benincasa

Senior Vice President, Sales and Marketing. Mr. Benincasa was a founder of Intelligent Medical Systems, Inc. ("IMS") in 1982, which developed, manufactured and sold the first infrared tympanic membrane thermometer, FirstTempTM and the GeniusTM product lines. The Company was acquired by American Home Products in January 1993. Prior to his twelve year career at IMS. Mr. Benincasa headed the sales forces for companies including Wyeth-Ayerst Pharmaceuticals and Hoffman-LaRoche Laboratories. He holds a Bachelor of Science in Pharmacy and a Masters in Pharmacology from St. Johns University. Mr. Benincasa joined U.S. Medical in February, 1994.

Scott M. Dolin

Vice President, Operations. For the past four years, Mr. Dolin was Director of Engineering for IMED Corporation, a San Diego-headquartered disposable medical device manufacturer. In this position he managed manufacturing engineering, plastics engineering, mold/tool engineering, equipment engineering, maintenance, pilot engineering and pilot plant groups in the San Diego and Mexico facilities, and oversaw all engineering efforts in IMED's Ireland manufacturing facility in support of manufacturing and developing medical disposable devices. His experience implementing cost improvement programs, new product transfers, total quality management, GMP compliance and ISO 9000 projects makes Mr. Dolin a significant addition to the U.S. Medical management team. Prior positions held at IMED between 1974 and 1988 include Director of Operations, Manager of Engineering, Reliability Engineer Manager, Engineeering Manager and Quality Manager for the IMED Ireland Limited subsidiary. Mr. Dolin also held the positions of Vice President, Operations at Solatrol Inc., and Plant Manager at Nypro San Diego between 1988 and 1990.

Sally Grigoriev

Vice President, Quality & Regulatory Affairs. Ms. Grigoriev joined U.S. Medical during the Spring of 1994, bringing more than 12 years of experience in the medical device industry. Most recently she was responsible for the implementation of the entire regulatory and quality systems at Block Medical, Inc. a Class II critical device manufacturer of disposables and electronic infusion pumps. At Imed Corporation, also a Class II manufacturer of electronic infusion pumps and disposables, she held many positions including Manufacturing Engineering Manager-Plastics Molding and Sub-Assembly, Quality Assurance Manager-Plastics and Instruments Manufacturing. Ms. Grigoriev has a Bachelors of Science degree in Chemical Engineering from U.C. Santa Barbara, and is an ASQL Certified Quality Auditor.

Carlos Manjarrez

Vice President, New Products, Research & Development. Mr. Manjarrez has been extensively involved in the design and development of SafeSnap since the Company's inception, and has been a full time employee of U.S. Medical since January, 1992. Previously, Mr. Manjarrez was Engineer and CAD Manager for Magor Molds, specializing in injection-molded medical products. His other experience includes Design Engineer/Owner of Falcon Engineering specializing in high-precision medical designs, and as a Mold Designer for the Kipp Group.

Charles E. Monts

Vice President, Finance and Administration. Mr. Monts, a licensed CPA, was most recently the Vice President/CFO of Overland Data, a San-Diego-based computer tape drive manufacturer. Overland Data grew during Mr. Monts' tenure from a \$3 million revenue base to over a \$35 million rate. During that six year period, the company completed two acquisitions and two venture capital financings. Prior to his employment at Overland Data, Mr. Monts held similar positions with companies in the electronics and publishing industries. His professional career in accounting began at Price Waterhouse.

P. Financial Proceedings (for the SafeSnap Product Line Only)

Management intends to raise more than \$15 million in equity financing through private transactions with accredited investors during the third quarter of fiscal 1995. A detailed financial analysis is presented in Appendix A, which includes pro forma income statements for the years ended 1/31/95 ("fiscal 1995", or "FY95") through fiscal year end 1/31/99 ("fiscal 1999", or "FY99").

It should be noted that these projections are solely for the SafeSnap line of products, and thus do not begin to consider the sales from additional devices either already in the early stages of production or under negotiation to be licensed, which would utilize SafeSnap's distribution channels and sales force. The proformas are based upon conservative pricing projections and thoroughly researched cost estimates.

The most significant assumptions used in the pro formas are as follows:

- SafeSnap Sales Price. The sales price of SafeSnap syringes are projected to be
 \$0.25 per unit throughout fiscal 1995, falling to \$0.14 during fiscal 1999 as a function of volume discounts and the Companies ability to recognize production economies of scale.
- * Production Capacity. The first set of 3cc multi-cavity production molds will be in use by August 1994. Additional sets of molds will be delivered continuously over the projected period, such that production capacity reaches 50 million units per month by the fourth quarter of fiscal 1999. The projections post fiscal-1995 assume sales equals to production capacity.
 - Cost of Goods Sold. The average cost of sales per unit declines significantly during the first quarter of fiscal 1996, when in-house automated assembly replaces some of the need for assembly at Nypro's and Kendall's Macquiladora facilities. Average cost of sales per unit declines throughout the next three years, reaching approximately \$0.07 per unit by the second quarter of fiscal 1997.

Based upon the sales volume described above, Management forecasts Earnings Before Depreciation Interest and Taxes ("EBDIT") to be as follows:

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3 0,103,003
\$ 16,131,000 - 12 12 12 17 19 1
\$ 25,875,000
\$ 29,400,000
1

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	1	U.S. Medical Instruments, Inc.	uments, Inc.		
بر بر	d.	Pro Forma Income Statement	e Statement		
		r.			
200	FYE 1/31/95		FYE 1/31/97	EYE 1/31/98	FYE 1/31/99
Units Sold Price/Unit	29,000,000	144,000,000 7.12 \$0.18	300,000,000	450,00	600,000,000 4
CGS/Unit	\$0.20	\$0.10	\$0.07	\$0.07	\$0.07
USMI Revenues Cost of Goods Sold	\$7,250,000	\$25,920,000 \$14,400,000	\$48,000,000 \$21,000,000	\$67,500,000	\$84,000,000 \$42,000,000
Gross Profit	41,416,000	000,026,114	000'000'77*	930,000,000	\$42,000,000
Operating Expenses Earnings Before Deprc., Int. & Taxes (EBD)	\$2,379,000 (\$961,000)	\$3.830.400 \$7,689,600	\$5.880,000 \$21,120,000	\$10,125,000 \$25,875,000	\$12,600,000 \$29,400,000
Depreciation & Amortization	\$626,000	\$1,219,000	\$1,268,000	\$1,902,000	\$2,853,000
Interest PreTax Earnings	\$425,000 (\$2,012,000)	\$843,000 \$5,627,600	\$1.446.000 \$18,406,000	\$1,446,000 \$22,527,000	\$1,446,000 \$25,101,000
Taxes	80	\$76.248	\$4.367.000	\$9,010,800	\$10,040,400
Net Income	(\$2,012,000)	\$5,551,352	\$14,039,009	\$13,516,200	\$15,060,60u
_			ر عه ۱ همر		
• The Company's Piscal Year Begins on 2/1 and Ends on 1/31,	1/31, thus Fiscal Year	thus Fiscal Year 1995 = 2/1/94- 1/31/95	101-420		

Revenues account for the SafeSnap Product Line Only

Malle Harouth

4.6 billian units. Today



U.S. Medical Instruments, Inc. (a development stage enterprise)
Report and Financial Statements
January 31, 1994

Price Waterhouse



Report of Independent Accountants

July 8, 1994

To the Board of Directors and Shareholders of U.S. Medical Instruments, Inc.

Pine Watehouse

In our opinion, the accompanying balance sheet and the related statements of operations, of shareholders' equity and of cash flows present fairly, in all material respects, the financial position of U.S. Medical Instruments, Inc. (a development stage enterprise) at January 31, 1994 and 1993, and the results of its operations and its cash flows for the years ended January 31, 1994 and 1993 and the period from June 19, 1991 (inception) to January 31, 1994, in conformity with generally accepted accounting principles. These financial statements are the responsibility of the Company's management; our responsibility is to express an opinion on these financial statements based on our audits. We conducted our audits of these statements in accordance with generally accepted auditing standards which require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for the opinion expressed above.

As described in Note 1 to the financial statements, the Company has incurred development stage operating losses since its inception. The company is currently seeking additional debt and/or equity financing in order to purchase additional capital equipment and meet its ongoing working capital requirements. The Company's business plan contemplates the acquisition of additional equipment and the commencement of mass production and sales of its initial product during the year ending January 31, 1995. Management believes they will be successful in obtaining such financing and achieving their business plan; however, if they are not, there is substantial doubt about the Company's ability to continue as a going concern. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Balance Sheet

	293,000 ated party 146,000 113,000 1,061,000 1,061,000 1,765,000 1,765,000 1,765,000 4,459,000 00 shares authorized, sued and outstanding actively 382,000 100,000	
		1993
Assets		
Current assets:		
Cash		\$ 324,000
Accounts receivable	\$ 2,000	3,000
Inventories		28,000
Prepaid expenses	7,000	
Total current assets	9,000	355,000
Property and equipment, net	2 479 000	1,069,000
intengible assets, net	-	345,000
Other assets	•	56,000
	\$ 2,791,000	\$ 1,825,000
Liabilities and Shareholders' Equity	•	,
Current liabilities		
Accounts payable and accrued expenses		\$ 240,000
Short-term related party notes payable	293,000	
Current portion of long-term debt to related party		
and other	• •	•
Accrued payroll costs	113,000	•
Total current liabilities	1,061,000	240,000
Long-term liabilities:		
Long-term debt to related party and other		
Deferred rent	17,000	
Total liabilities	1,765,000	240,000
Shareholders' equity:		
Preferred stock; 4,021,170 shares authorized;		
2,911,337 shares issued and outstanding		
Series A Convertible Preferred Stock	26,000	
Series B Convertible Preferred Stock	1,164,000	
Series C Convertible Preferred Stock	577,000	
Series D Convertible Preferred Stock	4,459,000	
Common Stock, no par value; 8,000,000 shares authorized,		
1,517,532 and 782,045 (pre-split) issued and outstanding		
at January 31, 1994 and 1993, respectively	·	4,025,000
Additional paid-in capital	•	
Deficit accumulated during development stage	(5,682,000)	(2,440,000)
Total shareholders' equity	1,026,000	1,585,000
Commitments and contingency (Note 7)		
	\$ 2,791,000	\$ 1,825 000

The accompanying notes are an integral part of these financial statements

Case 5.96 V. Distriments CAC Document 16 Filed 10/28/96 Page 117 of 212 (a development stage prise)

Statement of Operations

	Year ended January 31, 1994	Year ended January 31, 1993	Period from June 19, 1991 (inception) to January 31, 1994
Net sales	\$ 1,000	\$ 5,000	\$ 5,000
Costs and expenses:			
Manufacturing and start-up costs	\$ 525,000	366 000	992,000
General and administrative	1,049 000	£51,000	1,842,000
Selling and marketing	385,000	571,000	956,000
Research and development	1,116,000	249,000	1,823,000
Total costs and expenses	3,176,000	1,837,000	5,613,000
Loss from operations	(3,175,000)	(1,832,000)	(5,607,000)
Interest expense	67,000	8 000	75,000
Net loss	\$ (3,242,000)	\$ (1,840,000)	\$ (5,682,000)

The accompanying notes are an integral part of these financial statements

U.S. Medical Instruments, Inc.

(a development stage enterprise)

Statement of Shareholders' Equity

Statement of Shareholders' Equity							Case
Description	Cemmon Steck	Convertible Series A Prefetted Steck Steres: Ameunt	Correntible Series B Eleferred Steck Shares Amount	Convertible Series C Preletted Steck	Committee Series D Professer Stack Shares Amount	Additional Palatin Capital	Accumulanted derical during development A 0-9:0
Issuance of common stock for certain assets and costs of founders Issuance of common stock for cash, Argust 1991 to January 1992. Wil loss for the period from June 19, 1991 (inception) to January 31, 1992.	552,000 \$474,000						1187-J-CG (000 009)
Balence at January 31, 1992. Issuance of common stock for cash, February 1992 to June 1992. Issuance of common stock for cash, June 1992 to July 1992. Issuance of common stock for cash, net of refated costs of \$37,000, August 1992 to January 1993.	69,230 727,000 42,972 603,000 69,843 1,917,000						
Net loss for the year ended January 31, 1993 Balance at January 31, 1993	782,045 4,025,000						(1,840,000)
Five for one stock spilit Conversion of common stock into preferred stock Issuence of common stock per stock grant, August 1993 Issuence of Series D preferred for	3,128,180 (2,442,023) (3,726,000) 20,239 11,000	1,332,000 \$ 26,000	554,195 \$1,164,000	\$26,000 554,195 \$1,164,000 205,933 \$577,000 349,895 \$1,959,000	49,895 \$1,959,000		10/28/96
cash April 1993 to January 1994, not of related costs of \$99,000 finamen of common stock for canti-lenancy 1994 lawment of currents alock for services, January 1994 [Exercise of stark captions and other (Note 9)]	35,466 20,000 10,714 6,000 82,911 46,000			•	469,314 2,500,000	00000 013 00000	Page 118 of
Nel loss for the year ended January 31, 1994	1,617,532 \$ 382,000	1,332,000 \$ 26,000	554,195 \$1,164,000	205,933 \$577,000	619,209 \$4,459,000		(3,242,000) (4).2 5 (5.682,000) \$1.0

The accompanying notes are an integral part of these financial statements.

Case Medical Joseph Cocument 16 Filed 10/28/96 Page 119 of 212 (a development stage exprise)

Statement of Cash Flows

			Period from June 19, 1991
•	Year ended January 31, 1994	Year ended January 31, 1993	(inception) to Jenuary 31, 1994
Cash flows from operating activities:			
Net loss	\$ (3,242,000)	\$ (1,840,000)	\$ (5,682,000)
Adjustments to reconcile net loss to		• •	• • •
net cash used in operating activities:			
Depreciation of property and equipment	208,000	94,000	318,000
Amortization of intangible assets	120,000	11,000	132,000
Amortization of discount on notes payable	6,000		5,000
Non-cash charge for stock issuance	11,000		11,000
Common stock issued for research and development			322,000
Common stock issued for services performed	6,000		6,000
Common stock issued for preoperating costs			97,000
increase (decrease) in cash resulting from changes in.			•
Accounts receivable	1,000	(3,000)	(2,000)
Inventories	28,000	(28,000)	
Prepaid expenses	(7,000)	1,000	(12,000)
Other assets	(13,000)	(50,000)	(53,000)
Accounts payable and accrued expenses	269,000	240,000	509,000
Accrued payroll costs	113,000		113,000
Deterred rent	17,000		17,000
Net cash used in operating activities	(2.483,000)	(1,575 000)	(4,228,000)
Cash flows from investing activities:			
Payments for property and equipment	(1,624,000)	(1,025,000)	(2.780,000)
Payments for intangible assets	(9,000)	(326,000)	(335,000)
Net cash used in investing activities	(1,633,000)	(1,351,000)	(3,115,000)
Cash flows from financing activities:			
Proceeds from borrowings	1,126,000		1,126,000
Net proceeds from issuance of preferred and common stock	2,566,000	3,247,000	6,117,000
Net proceeds from issuance of warrants and other	100,000		100,000
Net cash provided by financing activities	3,792,000	3,247,000	7,343,000
Net increase (decrease) in cash	(324,000)	321,000	
Cash at beginning of period	324,000	3,000	
Cash at end of period	<u>\$</u>	\$ 324,000	<u>s</u> -
Supplemental information:			
Interest paid	\$ 62,000	\$ 8,000	\$ 70,000
Income taxes paid	\$ 1,000	\$ 1,000	\$ 3,000
Common stock issued to founders for:			
Property and equipment			\$ 24,000
intengible assets		•	\$ 31,000
Research and development expense			\$ 322,000
Reimbursement of preoperating costs			\$ 97,000

The accompanying notes are an integral part of these financial statements

NOTE 1 - THE COMPANY AND ITS CAPITAL RESOURCES

U.S. Medical Instruments, Inc. (the "Company") was incorporated in California on June 19, 1991. The Company's business is to design, manufacture and distribute safety medical equipment. The Company's initial product is a safety syringe which the Company plans to market to hospitals and medical product buying groups throughout the United States and worldwide.

The Company incurred a net loss of \$3,242,000 during the year ended January 31, 1994 and has an accumulated deficit during its development stage of \$5,682,000 at January 31, 1994. As of July 8, 1994, the Company has raised \$3,900,000 through additional equity financing (Note 10). The Company is currently seeking additional debt and/or equity financing in order to purchase additional capital equipment (Note 7) and meet its ongoing working capital requirements. The Company's business plan contemplates the acquisition of additional equipment and the commencement of mass production and sales of its initial product during the year ending January 31, 1995. Management believes they will be successful in obtaining such financing and achieving their business plan; however, if they are not, there is substantial doubt about the Company's ability to continue as a going concern.

NOTE 2 - SIGNIFICANT ACCOUNTING POLICIES

Inventories

Inventories are valued at the lower of average cost or market.

Property and Equipment

Property and equipment is recorded at cost and depreciated using the straight-line method over estimated useful lives of seven to ten years. Expenditures which substantially increase value or extend useful lives are capitalized. Maintenance and repairs are expensed as incurred. Leasehold improvements are capitalized and amortized over the remaining lease term.

Intangible Assets

Intangible assets are being amortized using the straight-line method over their estimated remaining useful lives of twelve years.

Revenue Recognition

Revenue from product sales is recognized upon shipment.

Research and Development

Research and development costs are expensed as incurred.

Income Taxes

Effective February 1993, the Company adopted Statement of Financial Accounting Standards No. 109 (FAS 109), Accounting for Income Taxes. The adoption of FAS 109 changes the Company's method of accounting for income taxes from the deferred method (APB 11) to an asset and liability approach. The asset and liability approach requires the recognition of deferred tax liabilities and assets for the expected future tax consequences of temporary differences between the carrying amounts and the tax bases of other assets and liabilities. The adoption of FAS 109 has no effect on the previously reported results of operations or financial position and the net loss for the year ended January 31, 1994.

NOTE 3 - COMPOSITION OF CERTAIN FINANCIAL STATEMENT CAPTIONS

	Januar	ry 31,
	1994	1993
Property and equipment: Machinery Injection molds Leasehold improvements Office equipment Equipment deposits (Note 7)	\$ 623,000 534,000 135,000 72,000 1,433,000	\$ 483,000 507,000 127,000 62,000
Accumulated depreciation and amortization	2,797,000 (318,000) \$ 2,479,000	1,179,000 (110,000) S 1,069,000
•	\$ 2,415,000	3 1,003,000
Intangible assets: Patents and license agreement Less accumulated amortization	\$ 366,000 (132,000) \$ 234,000	\$ 357,000 (12,000) \$ 345,000
Accounts payable and accrued expenses: Accounts payable Accrued expenses Bank overdrafts Other	\$ 320,000 132,000 51,000 6,000	\$ 240,000
	\$ 509,000	\$ 240,000

NOTE 4 - INCOME TAXES

No current or deferred tax provision was necessary for 1993 and 1994 due to net losses of the Company.

Deferred tax assets at January 31, 1994 are comprised of the following:

Description	Total		
Start-up costs capitalized for tax purposes Research and development costs capitalized for tax purposes Research tax credits Depreciation NOL carryforwards Other	\$	580,000 810,000 152,000 40,000 913,000 17,000	
	•	2,478,000	
Less deferred tax asset valuation allowance	(2,478,000)	
Net	<u>\$</u>	•	

The Company has Federal net operating loss carryforwards of approximately \$2,302,000 and \$3,000 as of January 31, 1994 and 1993, respectively. The Federal net operating loss carryforwards expire beginning in 2008. The state net operating loss carryforwards are \$1,151,000 and \$1,000 as of January 31, 1994 and January 31, 1993. The state net operating loss carryforward expire beginning in 1998. The Company also has research credit carryforwards for Federal and state tax reporting purposes totaling approximately \$99,000 and \$53,000, respectively, which expire at various times through 2009. As there can be no assurance that the deferred tax asset will be realized, a full valuation allowance has been provided.

In certain circumstances which are specified in Section 382 of the Internal Revenue Code, a 50 percent or more ownership change by any combination of significant shareholders (those owning 5 percent or more of the Company's outstanding stock) of the Company during any three-year period would result in a limitation on the Company's ability to utilize its net operating loss carryforward and realize the benefit of future tax deductions. Application of Section 382 to the ownership history of the Company indicates that any further significant changes in ownership could trigger a limitation on the utilization of the Company's operating loss carryforward.

NOTE 5 - LONG-TERM DEBT TO RELATED PARTIES AND OTHER

At January 31, 1994, the Company had long-term debt outstanding as follows:

Secured promissory note due to a shareholder, 60 monthly payments of \$18,100 with 8 percent interest per annum, maturing October 29, 1998; secured by certain manufacturing equipment	Amoun			
(net of discount of \$86,000 - Notes 7 and 9)	\$	777,000		
Secured note payable, 61 monthly payments of \$1,389, with 12.3 percent interest per annum, maturing May 15, 1998; secured by certain equipment		56,000		
	•	833,000		
Less current portion		(146,000)		
	\$	687,000		
The notes are payable as follows for the years ending January 31,				
1995	\$	146,000		
1996		161,000		
1997		176,000		
1998		193,000		
1999	_	157,000		
	\$	833,000		

NOTE 6 - CERTAIN RELATED PARTY TRANSACTIONS

A shareholder and director of the Company is also a partner in a professional firm providing legal and patent advice to the Company. The Company paid the professional firm approximately \$47,000 and \$100,000 during the years ended January 31, 1994 and 1993, respectively, for legal services. Amounts due to the professional firm for legal services at January 31, 1994 were \$50,000.

At January 31, 1994, the Company had outstanding short term notes payable to certain shareholders totalling \$293,000 with terms of up to 3 months bearing interest at 7.5 to 8 percent payable in cash or common stock purchase warrants (Note 9).

The secured promissory note due to a shareholder was also issued with detachable stock purchase warrants (Notes 5 and 9).

Upon its incorporation on June 19, 1991, the Company acquired certain assets and reimbursed certain costs of its founders in exchange for 552,000 shares of common stock (pre-split). The assets acquired consisted of patent application costs of \$31,000 and property and equipment of \$24,000. The reimbursed costs were charged to expenses during the period ended January 31, 1992; \$97,000 was allocated to preoperating expenses and \$322,000 was allocated to research and development in progress.

NOTE 7 - COMMITMENTS AND CONTINGENCY

In September 1993, the Company entered into a lease agreement for its headquarters and manufacturing facility. The term of the lease is five years and commenced January 1, 1994. The agreement provides for options to lease an additional 18,000 square feet at any time before June 1996 and to renew the lease for two consecutive periods of three years each and also contains certain abatement periods. Rent expense is recognized ratably over the lease term and minimum lease payments under the lease are as follows for the years ending January 31, 1995 - \$135,000, 1996 - \$180,000, 1997 - \$238,000, 1998 - \$245,000 and 1999 - \$231,000. Rent expense for leased property was \$79,000 and \$58,000 for the years ended January 31, 1994 and 1993, respectively.

During the year ended January 31, 1994, the Company placed purchase orders with suppliers of machinery and equipment totalling \$3,117,000. In conjunction with these orders, the Company has paid deposits of \$1,433,000 which is included in property and equipment and has remaining commitments of \$1,684,000. In conjunction with one deposit, the Company entered into a \$900,000 secured five-year shareholder promissory note with payments beginning 30 days after invoice date for receipt of equipment (Note 5).

During the year ended January 31, 1993, the Company paid \$250,000 to acquire the exclusive long-term license to certain patents, technical data and trade styles relating to its safety syringe. During the year ended January 31, 1994, the Company paid \$50,000 in minimum royalties related to this agreement. The license agreement also provides for payment of royalties based on product sales and stipulates a minimum royalty of \$125,000 and \$175,000 during fiscal years 1995 and 1996, respectively. The license agreement may be terminated by either party under certain circumstances.

The Company has an employee/shareholder agreement with a key employee/shareholder which provides for a maximum of \$540,000 to be paid to the employee/shareholder upon termination of employment.

Which or

NOTE 8 - SHAREHOLDERS' EQUITY

In April 1993, the shareholders approved a five for one stock split and increased the authorized shares to 12 million preferred shares and 8 million common shares. The stock split resulted in the issuance of 3,128,180 additional shares of common stock from authorized but unissued shares. The following preferred shares are issued and outstanding:

	January 31, 1994
Series A Convertible Preferred Stock (Series A), \$.002 per annum noncumulative dividend, no par value; 1,332,000 shares authorized, issued and outstanding at January 31, 1994	\$ 26,000
Series B Convertible Preferred Stock (Series B), \$.21 per annum noncumulative dividend, no par value; 937,150 shares authorized,	1.164.000
Series C Convertible Preferred Stock (Series C), S.28 per annum noncumulative dividend, no par value, 222,020 shares authorized, 205,933 issued and outstanding at January 31, 1994	1,164,000 577.000
Series D Convertible Preferred Stock (Series D), \$.56 per annum noncumulative dividend, no par value, 1,530,000 shares authorized, 819,209 issued and outstanding at January 31, 1994	4,459,000
Total Preferred shares	\$ 6,226,000

In April 1993, the shareholders approved a recapitalization plan whereby the common shareholders converted their common shares into Preferred Series A, Series B, Series C, or Series D, depending on the price originally paid for such common shares. All outstanding shares of Series A, B, and C and 349,895 shares of Series D were former common shareholders pursuant to this plan.

In the event of any liquidation, dissolution or winding up of the Company, the holders of Series A, B, C and D Preferred Stock shall be entitled to receive, prior and in preference to any distribution of any assets to the common shareholders, an amount per share equal to \$0.02, \$2.10, \$2.80 and \$5.60 plus an amount equal to all declared but unpaid dividends, respectively.

On or after April 30, 1996, the Company may, at the option of the Board of Directors, redeem in whole or in part the Series A, B, C and D Preferred stock by paying cash equal to the original issue price for each share, plus any declared but unpaid dividends on such shares.

Each share of Series A, B, C and D Preferred Stock is initially convertible into one share of Common Stock, at the option of the shareholder, at any time prior to redemption by the Company or automatic conversion. The conversion rate is subject to adjustment in the event of a stock split or stock dividend. The Preferred Stock has voting rights which are identical to the common stock voting rights, and automatically converts into shares of Common Stock immediately upon an initial public offering which results in gross proceeds to the Company exceeding \$3,000,000.

NOTE 9 - STOCK OPTION PLAN AND WARRANTS

During the year ended January 31, 1994, the Board of Directors approved a stock option plan ("the plan") which provides for the granting of options or stock purchase rights to employees, directors and outside consultants of the Company. Nonstatutory-stock options and incentive stock options may be granted at an exercise price not less than 65 percent and 100 percent, respectively, of the fair market value of the Common Stock, as determined by the Board of Directors, on the date of grant of such option. At January 31, 1994, options for 990,000 were available for future grant under the Plan.

During the year ended January 31, 1994, the Board of Directors granted 410,000 fully vested options to purchase shares of common stock with an exercise price of \$0.56; options to purchase 60,000 shares were exercised and no options were cancelled. At January 31, 1994, options for 198,540 common shares were exercisable under the Plan.

In connection with the issuance of short-term notes payable to directors and shareholders, the Company issued warrants to purchase 17,656 shares of common stock at \$0.56 per share. These warrants are exercisable at any time through December 2003. In connection with the issuance of a long-term note due to a shareholder, the Company issued warrants to purchase 50,000 shares of Series D Preferred Stock at \$5.60 per share. The warrants may be exercised at anytime through November 1998 (Note 5). The fair values of these warrants have been recorded as discounts to the related debt and are being charged to expense ratably over the debt repayment terms.

During the year ended January 31, 1993, certain key employees were granted non-statutory options to purchase 292,160 (post-split) shares of Preferred Stock at an exercise price of between \$2.10 to \$5.60 per share. All options were fully vested upon grant, none exercised and 30,000 were cancelled during the year ended January 31, 1994. The options expire at various times between April and June 1994.

In connection with the severance agreement of a director and a former officer of the Company, a warrant to purchase 22,911 shares of common stock was issued with an exercise price of \$0.56 which was exercised during fiscal year 1994.

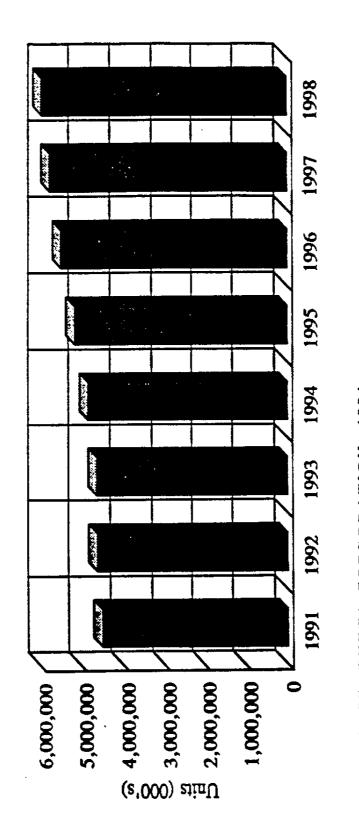
NOTE 10 - SUBSEQUENT EVENTS

The Company received \$3,900,000 from the sales of approximately 620,000 shares of Series D Preferred Stock and the exercise of 225,000 options to purchase shares of Series B Preferred Stock through July 8, 1994.

The Company placed additional purchase orders with suppliers of machinery and equipment totalling \$2,250,000 through July 8, 1994.

Total Syringe & Needle Market

UNIT SALES PROJECTIONS

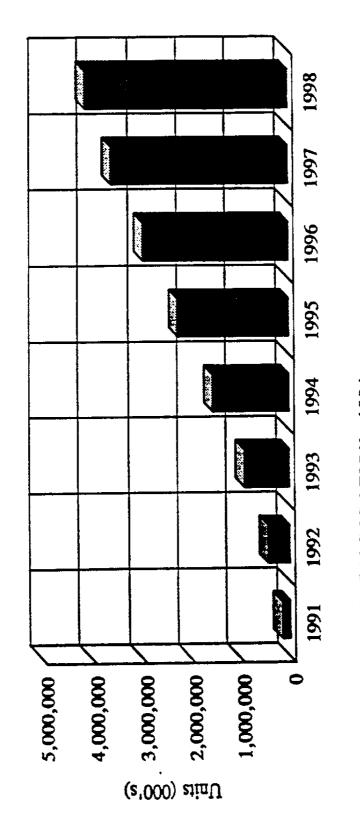


SOURCE: THETA CORPORATION, 1994

WS MEDICAL

Total Safety Syringe & Needle Market

UNIT SALES PROJECTIONS



SOURCE: THETA CORPORATION, 1994

US MEDICAL

EXHIBIT 2 -130-

Hypodermic Safety Syringe Market

UNIT SALES PROJECTIONS

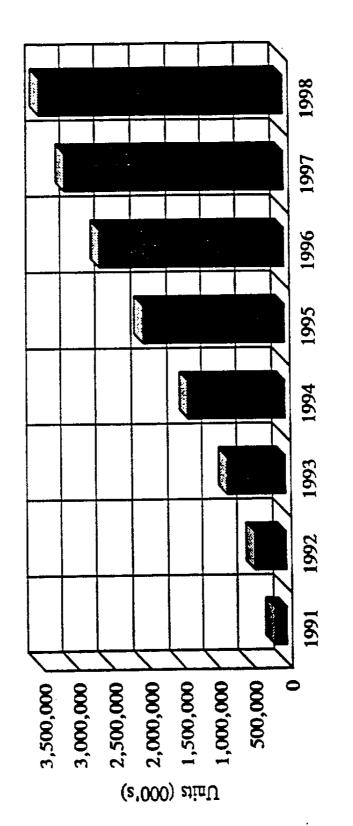
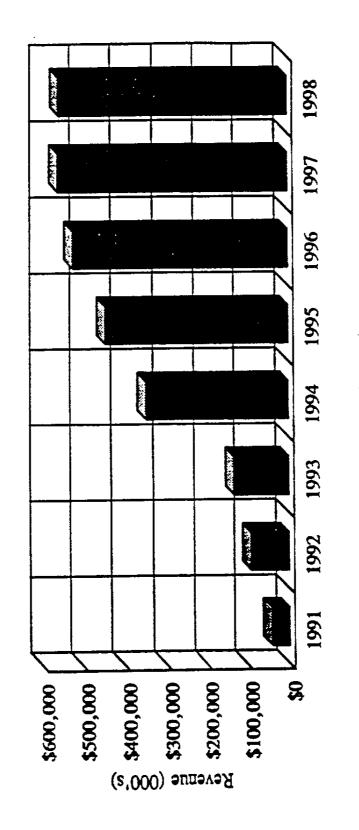


EXHIBIT 2 -131SOURCE: THETA CORPORATION, 1994

US MEDICAL

Hypodermic Safety Syringe Market

REVENUE PROJECTIONS



SOURCE: THETA CORPORATION, 1994

US MEDICAL

Selected Niche Markets

ACUTE CARE

- Emergency
- PACU (Post Anesthesia Care Unit)
- Pediatrics
- Psychiatrics
- Rheumatology

US MEDICAL

Selected Niche Markets

ALTERNATE CARE

Dialysis

Home health

• Immunization clinics

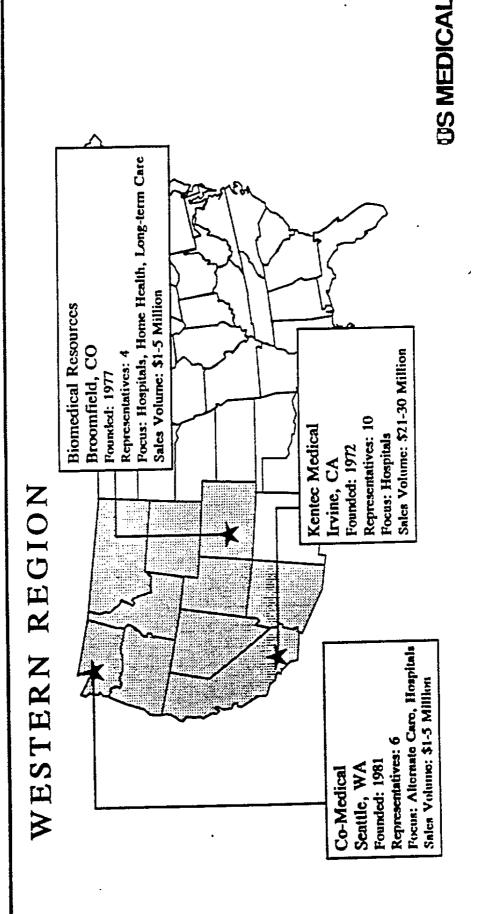
Long term care

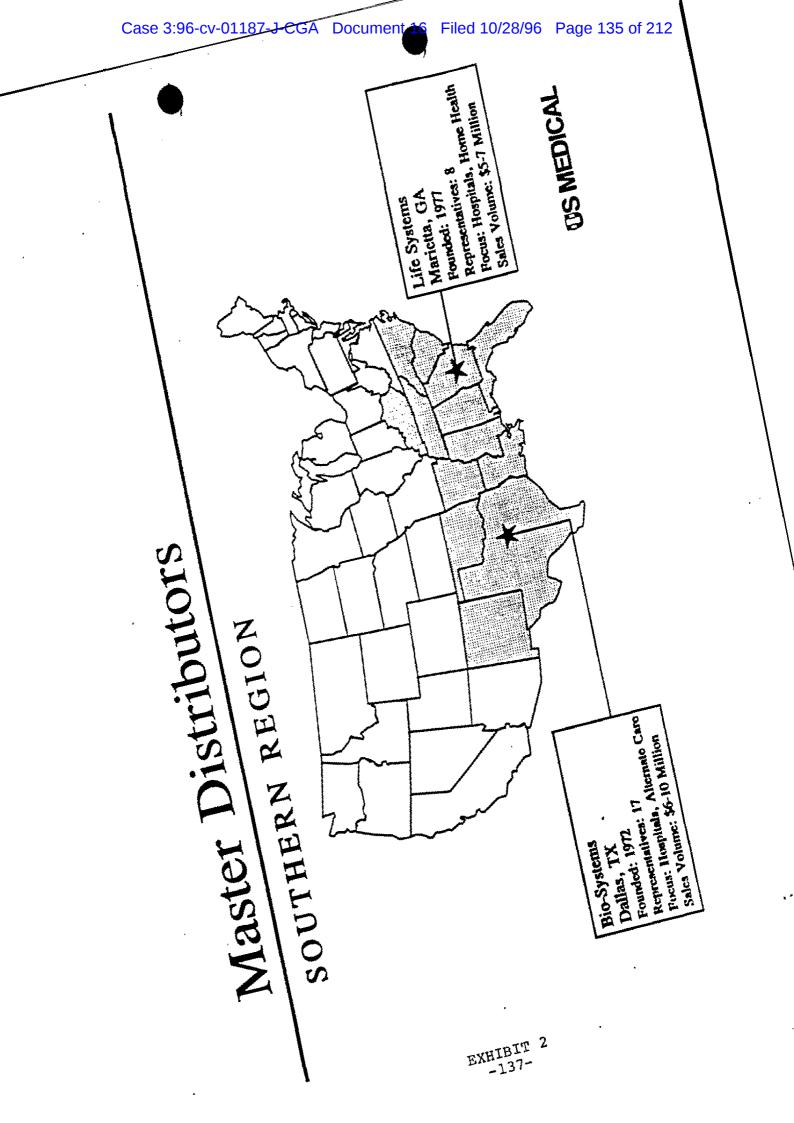
Outpatient care/ambulatory surgery

Safety Syringe

	,																	ICAL			
	Becton Dickinson	YES	YES	YES	YES	YES	YES	YES	YES	YES		YES		YES				US MEDICAL			
MATRIX	Sherwood Medical	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES				YES	YES	YFS				
PRODUCT	U.S. Medical				YES	\ YES	YES	YES	YES		YES /	/ YES	XEX /	0 /				O Available September 15	· ()	· · bedoom	
E		29G 1/2"	27G 1/2"	25G 5/8"	Syringe Only	25G 5/8"	23G 1*	22G 1 1/2"	22G 1"	21G 1 1/2"	21G 1"	Syringe Only	22G 1*	Syringe Only	Syringe Only	ZIG 1 1/2" /	20G 1 1/2"		X.5 (IM) bear	5	•
COMPETITIV	Syringe Size	1cc Insulin	1cc Tuberculin		300		•					5α		10cc	12cc			☐ Available December 1	5.X.	* \ \	
-	\	\	_				•	•				_	/	/			`\			/	

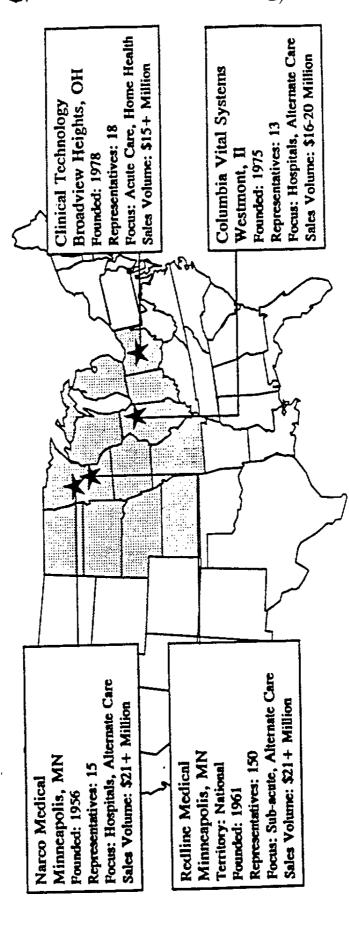
Master Distributors





Master Distributors

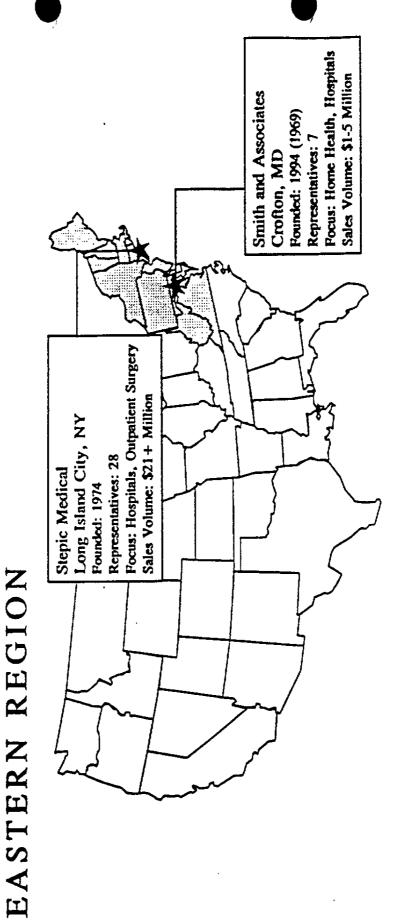
CENTRAL REGION



WS MEDICAL

WS MEDICAL

Master Distributors



Master Distributors

@S MEDICAL Johns Hopkins Home Care Group Physicians Memorial Hospital Memorial Sloan Kettering Columbia Presbyterian Shriners Hospitals for Crippled Children REGIONAL KEY ACCOUNTS Baylor University Medical Center University Hospitals, Cleveland Kimberly Home Health Care University of Cincinnati Children's Hospital Parkland Hospital South Central (control of the University of Washington University of California Kaiser West

MPS/June 1995



Marker Beat

Cost of protection probed by infection control survey

DEERFIELD, IL — Concerns over HIV and TB transmission, as well as increasing regulatory pressures to protect workers, are fueling many of the infection control product decisions in hospitals today.

In early 1993, MPS's sister publication Hospital Purchasing News mailed surveys on infection control trends to 1,000 ma-

terial management professionals in hospitals across the United States; 306, or 31%, of the surveys were returned. Among bed sizes, 47% came from facilities with up to 200 beds; 30% from 201-400 beds and 22% from facilities with more than 400 beds.

Nearly half of respondents said their facilities had purchased safety needles during the past year. While 30% said they had not purchased

such devices, 14% said they plan to do so by mid-summer.

Meanwhile, slightly less than half of the respondents (43%) said their facilities had purchased needleless systems to administer IV drugs during the past 12 months.

Close to one-fourth of the respondents said they plan to do so within the next six months, while another 26% said they have not purchased the devices in the past year.

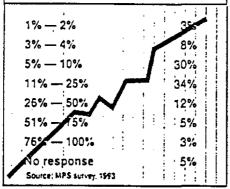
PPE purchases climbing

Among those products most hospitals expect to buy more of this year are masks, goggles and eye shields, fluid-resistant surgical apparel and exam gloves.

Other popular choices of infection control products hospitals

Dealer sales

Range of infection control product sales increases in previous year, from 100 respondents



expect to buy more of in the coming year are sharps disposal containers (38% said so), surgical gloves (25%), shoe covers (20%) and scope disinfectants (21%).

Less-popular infection control products were sterilization indicators and monitors, surface disinfectants, surgical scrubs, antimicrobial soaps and automated scope disinfector equipment.

Concerns over allergic reactions to latex have seen height-

ened interest in hypoallergenic gloves. Seventy-three percent of respondents said they have purchased more hypoallergenic gloves the past year than the year before. Twenty-four percent said their facilities' level of hypoallergenic glove purchases remained the same during the previous 12 months.

Still, hypoallergenic gloves make up less than I out of every 10 most hospitals buy, according to the survey.

Thirty-eight percent of the respondents said between 1% and 5% of their facilities' total gloves are hypoallergenic, 28% said the percentages fell somewhere between 6fr and 10%, while 21% of the respondents said hypoallergenic gloves comprise 11% to 25% of their total glove purchases.

Concerns about TB mixed

Fifty-four percent of respondents said concern about TB has increased in their facilities the past 12 months, while close to an equal amount (45%) said concerns over TB have remained stable.

Protective equipment for high-risk areas, such as dust-mist-fume respirators (DMFRs) and battery-powered air purifying respirators (PAPRs), are not used by a majority of hospitals.

Sixty-six percent said their facilities have not purchased DMFRs during the past 12 months, and an even higher percentage (77%) said they had not purchased PAPRs.

Disposables still reign

Disposable surgical gowns for virtually all applications are still the product of choice among most surgeons, while a mixture of disposable and reusable gowns describes surgeon preference among only a fraction of respondents.

Product cheice, influence

Close to half of the respondents said they are participating more on infection control committees than they did a year ago, while none of the respondents said their roles have diminished.

While infection control practitioners (ICPs) exert a great deal of influence on product selection, they do not act alone, according to the survey.

Seventy-eight percent of the respondents said if their ficilities have a full-time ICP nurse or supervisor, that individual sits on a product review and selection committee with voting privileges. Fifteen percent of the respondents said the ICP consults with the material management department, which has final authority.

Case 3.96-cv-0118z-J-CGA Document 16. Filed 10/28/96 Page 140 of 21.

Respondents' makets

The majority of respondents' customers:

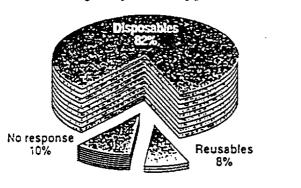
Hospital 66%

Nursing home 12%

Other22%

Gowns

Your customers' gown purchasing preference is for:



TB concerns

Your customers' concerns about the spread of tuberculosis in the past year have:

Increased 58%

Decreased 2%

Stayed the same 35%

No response 6%

Totals to not equal 100% but to rounding

Purchasing patterns

Customer purchasing patterns over the past year by individual product

,			Stayed	No
	Increased	Decreased	the same	response
Mzsks/goggles/eye shields	82%	2%	652	11%
Fluid-resistant surgical apparel	74%	1%	11%	14%
Exam gloves	62%	2%	22%	14%
Sharps disposal containers	56%	2%	26%	14%
Scope disinfectants	31%	2%	49%	18%
Surgical gloves	35%	3%	43%	19%
Surface disinfectants	58%	3%	25%	15%
Shoe covers	28%	4%	52%	17%
Surgical scrubs	28%	2%	50%	19%
Anti-microbial soaps	56%	2%	25%	15%
Safety needles	59%	2%	23%	17%
Needleless IV systems	52%	3%	30%	15%
Hypoallergenic gloves Totals do not equal 100% due to rounding.	72%	3%	10%	15%

Source: MPS survey, 1993

Case 3:96-cv-01167-1-CGA Documen

AND CALIFORNIA



PHGIOS BY IANZE MESSEN/THE CHRONICIE

ormer nerse Melissa Compbell lay dying of AIDS

Worders Demand Safer Needles

Some hospitals begin to offer new AIDS-protection equipment

By Sabin Russell Chronicle Staff Writer

Pressured by unions and prompted by changes in federal law, hospitals are starting to respond to demands by health care workers for safer needles in the era of AIDS.

Despite an apparently low rate of accidental infections, and mounting concern over health care costs, hospital administrators are more willing to pay for a new array of devices designed to protect nurses and laboratory technicians from accidental needle sticks.

"As soon as they are out on the market, we'll get them," said Dr. Julie Gerberding, who heads the AIDS infection control program at San Francisco General Hospital.

Facing a formal complaint from employee unions, the hospital last year reluctantly adopted a catheter needle that automatically retracts into a protective sheath—a device previously used only in the emergency room. This year, the hospital is switching its entire inventory of hypodermic needles

inventory of hypodermic needles to self-sheathing devices.

The average cost of the new needles is five times that of the devices they are replacing. The new retractable catheter needles, for example, cost \$1.50 each, compared with 50 cents each for the old version.

Gerberding concedes that the initial approach hospitals took toward infection control — a long list of do's and don'ts — was not working well enough. After research showed that better equipment could make a difference, "manufacturers became enthusiastic," she said. In recent years, more than 300 patent applications have been filed for a variety of safer devices.

Accidents Could Bo Reduced

Experts estimate that half of needle stick injuries could be eliminated with the use of new devices that minimize exposure to sharp points. Self-sheathing hypodermic needles and catheter connections are available but are not yet in widespread use.

"We're trying to bring enough hospitals on-line so that the prices come down," said John Mehring. AIDS coordinator for the Service Employees International Union's western region.

Mehring is optimistic that infection-control standards at hospituls are tightening, particularly since federal Occupational Safety and Health Administration rules took effect this summer. The new rules require use of protective gear such as gloves, and back the use of safer needles.

Supporting such changes are new studies confirming that exposure to blood through needle sticks, cuts and spisshes is commonplace among health care workers. In a report last month, University of California at San Francisco professor Kathlean Turner-Hubbard disclosed that Marcent of medical students and 35 percent of dental students in the UCSF class of 1993 had been accidentally exposed to blood last year.

Her report cited student fatique and inexperience as a major factor placing them at risk for needie sticks. "They frequently had been assigned tasks in which they had minimal training," said Turner-Hubbard.

About 15 percent of all nurses receive accidental needle sticks

each year, several studies show. Chiya tiny fraction — about three in 1,000 needle sticks — are believed to transmit the AIDS virus to health care workers. But those who have such accidents live in fear until their tests come in.

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Safer Hypodermic Needles

Hurse infected by Keedle Stick

Melissa Campbell knows the horror of an accidental needle stick.

Five and a half years ago, while working as a nurse in the AIDS unit of Kaiser Hospital in San

F-Francisco, she gave a patient an injection, crossed her hands while removing the needle and jabbed herself.

"I had just felt that it wasn't going to happen to me," said Campbell. "I felt pretty safe."

Campbell took two AIDS tests with no signs of infection, and assumed she was out of danger. But in 1990, her health mysteriously began failing. She suffered nausea and neck spasms. Her doctor thought it was Parkinson's disease. A year ago this month, she tested again. Not only did she have the AIDS virus, her immune system was already shot.

"I knew something was really wrong;" she said. "In some ways, I was just relieved to know what it was."

Today, Campbell, 29, is confined to her bed at the home of a friend in Martinez, her thin frame wracked by fevers and tremors, her hands and feet seared by the pain of nerve damage. Campbell wants to make her plight known, so her suffering can serve 25 a warning for her colleagues to remain careful, and for hospitals to take more care.

"We've got to push to have safe needle devices... and adequate training to be able to use them," said Campbell.

Lobbying for Sofer Equipment

- Nurses infected on the job have been lobbying behind the scenes, using assumed names like Jane Doe and Jean Roe, to educate their peers and call for change.

"You don't have to work in an AIDS ward to become infected," said "Pat Doe," a former nurse at San Francisco General Hospital, who found out she had become infected when an insurance company notified her of blood-test results. The nurse will never know for sure how she was exposed, but believes it may have occurred in

the early 1980s when she was splashed with blood while reconnecting a catheter to a homeless patient in the intensive care unit.

Pat, who does not want her real _name disclosed_lectures about her -experience to other nurses. "I

don't mind telling them that a lot of health-care workers are sloppy," she said. "I like to tell them to please be careful."

In response to concerns about AIDS, hepatitis B and other blood-borne infections, surgeons are

adopting so-called universal precautions to create barriers to blood contact. Some surgeons today approach the operating room wearing the equivalent of a raincoat, rubber boots and double layers of latex gloving.

"The underlying principle of universal precautions is that blood is a toxic substance," wrote Dr. William Schecter, a San Francisco General Hospital surgeon.

Despite the risk of blood exposure, the number of reported cases

of AIDS transmission to health-care workers throughout a decade of the epidemic has been low. The federal Centers for Disease Control in Atlanta last month reported that 32 health care workers in the United States have been infected with the AIDS virus by on-the-Job accidents and seven of those have developed full-blown AIDS. An additional 69 infections are listed as "possibly occupationally acquired."

Cases May Be Undarraported

However, the federal agency acknowledged that the actual number of cases may be much higher because workers may elther be unaware of the exposure or reluctant to disclose it in fear of losing their jobs.

"I personally feel the number is gravely underestimated," said "Jean Roe," another Bay Area nurse who was infected on the job. "I talk to health-care workers around the country, and I personally know enough that were infected to make up balf the federal total."

Jean, who was infected when she was stuck by a needle purportedly left at a patient's bedside by a careless doctor, said she believes hospitals need to do more to provide safe equipment.

"People need to stop looking at the cost of a syringe versus the cost of someone's life," she said. "When you see a friend who was stuck by a needle dying, how can you walk away and say it's not cost-effective to put a safer device in place?"

Infected Nurse Wins \$5.4 Million From New York State in AIDS Suit

By SAM HOWE VERHOVEK Special to The New York Times

ALBANY, July 14 - A judge has ordered New York State to pay a Utica nurse \$5.4 million after she contracted the virus that causes AIDS from a prisoner during a frenzied scuffle at a hospital in 1985. The judge determined that two corrections officers assigned to the prisoner had done nothing to restrain him as he punched and kicked at a medical team and the nurse was Jabbed with a hypodermic needle containing his infected blood.

The decision, by a Court of Claims judge in Binghamton, includes the largest pain-and-suffering award the state has ever been required to pay a victim. Legal experts said today that they believed it was one of the largest civil awards in the country to result from a person's being infected with H.I.V., the virus that causes AIDS.

Graphic Description

The ruling was unusual in its graphicdescription of the events leading to the infection, including testimony from a fellow nurse who described the look of horror that crossed the plaintiff's face as the infected needle plunged into the palm of her hand.

But it was notable also for the anger expressed by the judge, Israel Margolis, who said testimony from the medical team left him convinced that the incident could easily have been avoided if the prison guards had done their duty rather than standing in the hallway observing the thrashing, One of the nurses on the team testified that she repeatedly screamed "Get the hell in here!" and "Do your damn job!" at the guards but that they ignored her.

The plaintiff, a 38-year-old mother of three who was referred to only as Jane Doe in court papers, has a "reasonable life expectancy" of five years, the judge wrote.

'For any mother, that contemplation of the loss of enjoyment of seeing her children mature and marry is a suffering that is nearly immeasurable," he said. "For this one, who is so

devoted to her family and obviously loves children so much, the suffering is particularly massive.

The judge also found that the inci-dent had "deprived her of a happy social life with her husband," adding: "It palls every outward sign of affec-

State officials said today that the incident, while unfortunate, was less straightforward than the judge had portrayed it. Neither of the guards has been disciplined, and the state said it would appeal the verdict,

A spokesman for the Department of Correctional Services, James Flatexu, said the appeal would be based in part on the contention that the hospital should at least share in liability. Another nurse had grabbed the needle in an effort to throw it off the prisoner's bed just before he kicked her, and the needle was plunged into her colleague's hand.

Demands for Assistance

The incident occurred in August 1988 after the prisoner, identified in court papers as John Smith, 28, was transferred from the Mid-State Correctional Facility in Marcy to Faxton Hospital in Utica. He was serving a 21/4-to-5-year term for possession of stolen property.

While in the hospital, Mr. Smith apparently suffered a grand mal selzure in which he shock violently, While most patients enter a period of relative calm after such an episode, Mr. Smith became "more combative, irrational and bizarre," according to hospital workers at the scene.

'He was just like — 1 don't know. all I could think of is a rabid dog, how they go out of their head and don't know what they're doing," testified

one nurse, Mary Kimball.
Although the struggle with Mr. Smith played out intermittently over a half hour, the doctors and nurses testified - and the judge agreed that the two guards did not come to help. At one point the guards asked where they could find gowns, gloves and other protective gear, and a nurse beckoned to a table across the room, but the guards did not put the garments on.

NEW YORK TIMES July 15, 1992

"Multiple, unanswered demands for assistance were made of these two corrections officers to intervene in a timely fashion and were effec-tively and utterly refused," Judge

Margolis said.

One of the guards, Runald Po-tempa, refused to discuss the incident with a reporter, his mother said by telephone today. No phone number could be found for the other guard, Timothy O'Conner, and a spokesman for Council 82, the state corrections officers' union, did not respond to messages left at his office.

The prisoner died of what was listed as congestive heart failure one day after the incident. The nurse initially tested negative for the virus that causes AIDS and had continued sexual relations with her husband, Several months later, she tested positive. So

far, he has not.

'Nice People Don't Have It'

The nurse was awarded \$4.25 million for pain and suffering, and her husband received \$1 million for loss of consortium. The balance of the award was for lost wages and medical expenses.

In discussing the particular misfortune in the case, Judge Margolis included extensive portions of testimony from the nurse herself, who told him she remained reluctant to tell anyone outside of her family that she had the virus.

"This disease has a stigma," she told the judge. "Nice people don't get it. If you have this disease you are obviously an addict or a prostitute or you did something bad. Nice people don't have it.

"People are very afraid of this disease," she continued. "They don't understand how it's transmitted. Even medical people.

"I have a nurse on the floor who I worked with for seven years, and she was present the day the needle stick happened. She wasn't in the room, but nappened. She wasn't in the room, but she was present on the floor that day, and about two years ago she asked me how this whole thing turned out and I just said, "Well, do I look like I'm sick?' and she said, "Well, that's good, because," she said, 'I think if you had AIDS I excidn't work with you," and this is a general consensus."



American Medical Association

NOVEMBER 16, 1992

HIV infection of medical workers

ATLANTA-On-the-jobaccidents have led to HIV infection in 32 health care workers — mostly lab technicians and nurses — and are suspected of infecting 69 others as of Sept. 30, the CDC reports. Twenty-seven of the 32 workers were infected by needlestics or scalpel cuts; seven, or 22%, have developed AIDS. The 69 others are linked with workplace exposures because they reported no other known risks; 54 of those have developed AIDS. The CDC notes there may be scores of other cases that have not been reported.

THE SAN DIEGO UNION-TRIBUNE . SATURDAY, AUGUST 8, 1952

AIDS syringe mix-up nets woman \$1 million

BY CHERYL CLARK Staff Writer

A San Diego weman who was injected with a syringe previously used on an AIDS patient will receive more than \$1 million from Mercy Hospital in a settlement of her lawseit.

The amount of the settlement. achieved in May, was not made public, but the figures appear in documents obtained by The San Diego Union-Tribune.

The min-up occurred in September

1990 when the 23-year-old woman was

at the hospital seeking treatment for back pain. A technician in the nuclear medicine department preparing her for a bone scan mistakeniy used a syringe that had not been discarded after being ap-plied to another patient, who had AIDS.

The U.S. Centers for Disease Control (CDC) cited the Mercy incident and two others elsewhere yesterday as it issued stricter recommendations for how medical facilities should handle the radioactive materials used in nuclear medicine.

It is not known if the San Diego pa-

tient, who has not been identified, is infected with the AIDS virus. Patients in the two other cases noted by the CDC - one in the Netherlands and one in Albuquerque, N.M. - did become infected.

"These incidents were totally pre-ventable and involved human error," said CDC epidemiologist Jacquelyn Polder, who came to San Diego two years ago to investigate the Mercy incident.

They are all explained by health providers not carefully checking and match-

ing carefully the name of the patient to

the specimen," Polder said.

Mary Yarbrough, Mercy's interim
president, said through a spokeswoman yesterday that the hospital has conducted a stringent review of all policies and procedures within its nuclear medicine department and changed several of them. The spekeswomen couldn't say if they now parallel the CDC's new guidelines because hospital officials had not yet seen them.

The CDC guidelines, published in the

current Marbidity and Martality Weekly Report, call for a two-person checking system in which a patient's identification number is always cross-checked with the product to be injected.

The CDC also recommends assigning a second identification marker to each patient to guard against mistakes between two patients with the same name; as happened with one of the three cases;

cited by the CDC, Polder said.

The agency also urged additional training of all health-care providers in universal infectioncontrol procedures and more stringent labeling and documentation of products and their linjection into patients.

Polder estimated that accidents of all types occur when administering nuclear medicine material either through errors in patient identification or dosage at the rate of once in 10,000 procedures.

Mistakes may be more likely in nuclear medicine departments than others, Polder said, because procedures there often involve withdrawing a patient's blood cells, marking them with a radioactive isotope and then reinjecting the cells into the patient.

THE RESERVE OF THE

"These incidents were totally preventable and. involved human error."

JACQUELYN POLDER CDC exidemiologist

The transfer of the section

Preparation of the injectable material occurs beforehand and in a different location than where the patient receives the injection, so "the material needs to be labeled to be absolutely certain, Polder said.

A state report on the Mercy incident said that hospital officials became aware of the accident two hours after it occurred, but didn't notify the patient for another, 34 hours, when she was summaned to the hospital at 1:30 a.m. to discuss the incident.

According to her atterney, Harvey Levine, the woman has suffered tremendous mental anguish since then. She has been periodically tested to determine whether antibodies to the AIDS virus have appeared, Levine said.

Documents related to the settlement indicate that the woman received \$600,000 at the time of the settlement May 11 and will also get \$2,300 a month for Efe. If the woman dies, the payments remaining in a 20-year period will

go to the person she designates.

A spokeswoman for Mercy Hospital declined to comment on the settlement, saying the hospital had agreed with the woman and her attorney not to discuss it.

Dr. Michele Ginsberg, emiemiologist for the county Department of Health Services, said the CDC's investigation Elustrates how different medical departments require specific infectioncontrol guidelines.

"My impression is that before these episodes were recognized in nuclear medicine, people were not examining that area as needly as they are examining it now.

Ginsberg said.

THE NEW YORK TIMES METRO THURSDAY, JANUARY 14, 1973

NEW YORK STATE

Doctor Sues Syringe Maker in H.I.V. Illness

A doctor has sued a manufacturer of hypodermic syringes, contending that she was infected with H.I.V. after she accidentally pricked her finger while recapping a needle used to draw blood from a hospital patient.

The doctor, a psychiatrist who lives in Manhattan, is identified in court papers only as Jane Doe. The manufacturer, Becton Dickinson & Company, filed papers on Monday to move the case from State Supreme Court to Federal District Court in Manhattan.

The suit blames a defect in the design of the needle for the doctor's infection. It said the incident occurred in 1986, when she was 25 years old and serving her first month of an internship and residency program at a Manhattan hospital. The hospital was not identified.

The suit asks for compensatory damages of \$100 million and punitive damages of \$1 billion. The doctor's lawyer is Lawrence C. Moss.

The case recalls the 1990 trial of Dr. Veronica Prego, who sued the city's Health and Hospital Corporation, contending that she was stricken with AIDS after pricking her finger on a needle used to draw blood from an AIDS patient in Kings County Medical Center in Brooklyn in 1983. Dr. Prego settled the case for \$1.35 million.

A lawyer for Becton Dickinson, Leslie Gordon Fagen, said, "we have reviewed the plaintiff's filing and the company does not believe that it bears any responsibility for the tragedy alleged in the complaint."

Needlestick Injury in the OR: Facts and Prevention

By Ahmad M. Mansour, MD

coidental needlesticks to nursing personnel have become a matter of great concern because of the potential for mansmission of hepatitis B virus, human immunodeficiency virus (HIV), and other nosocomial infections (Table 1). Because of the seriousness of these infections, a retrospective review of needlestick injunes was conducted for a period of 4.3 years to determine the needlestick injury rate among nurses working at various sites. The majority of needlesticks occurred on the inpatient floors (73.5%), and 4.8% occurred in the operating room. The guidelines for prevention and management of such injuries are presented. In addition, the risk of needlestick injury among nurses at various sites of work is analyzed, and recommendations for prevention are presented.

Results

Between November 1, 1984 and January 31, 1989, the number of nee-

November 1989

The average annual incidence rate of puncture wounds was highest among OR nurses.

dlestick injuries reported at the University of Texas Medical Branch Hospitals. Galveston, Texas, was 1,053. Of these injuries, 61.6% involved the nursing staff, amounting to 649 injuries. The majority (73.5%) of injuries occurred on the inpatient floors, followed by the outpatient clinic (9.2%), the emergency room (6.0%), and the operating suite (4.8%) (Table 2).

Discussion

The risk of transmission of HIV and hepatitis B virus after a needlestick has been estimated to be as high as 1% and 25%, respectively. 1-3 The risk for transmission of these infections is far from negligible, especially when dealing with high-risk patients. High-risk patients include those with acute virul hepatitis, male homosexuals, percutaneous drug abusers, hemodialysis patients, immunosuppressed patients, institutionalized mentally retarded persons, and recipients of multiple blood

NEEDLESTICK INIURY

TABLE 1 NOSOCOMIAL INFECTIONS TRANSMITTED BY NEEDLEPRICKS

AIDS
Hepatitis B
Syphilis
Malaria
Tuberculosis
Staphylococcus aureus
Streptococcus pyogenes

TABLE 2 SITE OF OCCURRENCE OF NEEDLESTICK INJURIES AMONG NURSES

Operating 31 (4.8%) Room inpatient 477 (73.5%) Laboratory 24 (3.7%) 60 (9.2%) Outpatient Emergency 39 (6.0%) Room Not Specified 18 (2.8%) 649 Total

transfusions.

As in other series, the nursing staff accounted for the majority of needlesticks. 4-5 Although the total number of puncture wounds was highest on the inpatient floors in the present series and in others, the average annual incidence rate of punctures per 100 nurses was

TABLE 3 NEEDLESTICK PREVENTION STRATEGIES

- · Education and information
- · Get the hepatitis B vaccine and the tetanus immunitation
- Obtain assistance when dealing with uncooperative patients.
- · Good lighting conditions
- · Avoid recapping procedures as much as possible
- · Avoid overfilling disposal containers
- Avoid leaving loose needles or needle sutures outside the disposal containers
- · Remove needles and sharp tips with a needle forceds
- Keep snarp instruments in their protector snield until immediately before using
- Arrange sharp instruments with tips directed towards one side of the table
- Avoid wiping sharp tips with your fingers; instead use a brush or a gauze mounted on a forceps
- Warn others that you are handling sharp instruments and ask for special care in the transfer of such instruments
- Avoid quick handling of sharp instruments (especially during emergencies)
- Double gloving does not protect against needlepricks, nor are leaded gloves used in encologic surgery
- Use of thimbies (plastic or metallic) can protect the operator as most injuries occur around the fingertips
- Stainless steel gloves can offer additional protection

highest in the operating room (30 punctures per 100 nurses1. The activities leading to the needle-puncture included recapping needles (25%), disposing of needles into receptacles (32%), administering medications or withdrawing blood (25%), and miscellaneous activities (24%).4 With the implementation of rigid, puncture-resistant container systems, the majority of punctures became procedure-related (such as during venipuncture or the removal of intravenous lines), followed by recapping. Only a minority of injuries occurred during disposal.5 Factors that are known to increase the chance for

puncture wounds during a procedure include dealing with uncooperative patients without having assistance, working under poor lighting, increased fatigue or nervousness, night shifts, lack of experience, and quick handling of needles in emergency procedures.

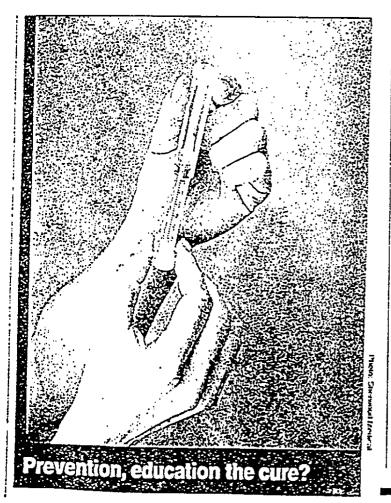


EDITORIAL

Purchasing



ORPN/January 15, 1993



ORs slow to report exposures: experts

by John Hall

Next to ERs, operating rooms are arguably the hospital departments most exposure-prone to blood-borne pathogens. Yei, they are least likely to report such incidents, a phenomenon supported by a leading hospital-based public health researcher. OR directors and indirectly by numerous recent studies.

The OR is an environment in which every nurse and physician incurs an average of two to three sharps injuries a year. Yet many of those injuries fall through the cracks of a system hospitals are just now beginning to fully assimilate — the OSHA bloodborne pathogen regulations.

Only last June did the Occu pational Safety and Health Administration begin requiring hos pitals to keep records of exposure incidents. Months or ever years may pass before that agency, as well as the Centers for Disease Control and Prevention, fully understands the level of exposures occurring in hospitals. Even then, some say, their data may be seriously flawed.

Some blame the underreporting in the OR to overkill. Nurses and doctors, they say, spend most of their day being splashed by blood and other body fluids and view it as a routine part of their jobs.

Others attribute it to a misun-See OR exposures, p. SI4.

OR exposures

Continued from page \$1.

derstanding of what the OSHA regulations deem as an exposure. As defined in the regulations, "occupational exposure means a reasonably anticipated skin, eye, mucous membrane, or parenteral contact with blood or other potentially infectious materials that may result from the performance of the employee's duties." Such exposures must be reported without regard to personal protective clothing or equipment.

Still others attribute it to fears, especially among surgeons, that their careers would be jeopardized if an exposure incident ever became public.

None will dispute, however, that the risks of blood-borne exposures are very real: According to OSHA, more than 200

health care workers die each year as a result of exposure to the Hepatitis B virus; a smaller number die after contracting the HIV virus that causes AIDS Infections eventually occur in one out of every three HBV-B exposures; HIV infection occurs in roughly one out of every 250 exposures to the virus.

Compounding the problem is the fact that chronic carriers of the HBV-B virus are difficult to identify. In fact, roughly

90% of such carriers admitted to hospitals are not identified. Similarly, while HIV testing of hospital patients is commonplace, a newly tested patient with a negative test result may actually carry the virus, according to the American Medical Association.

In a 1991 study published in the Journal of the American Medical Association, researchers studying surgical procedures at Atlanta's Grady Memorial Hospital found that over a period of six months, OR personnel were at significant risk for infection from bloodborne pathogen exposure; at least one blood contact was, observed in 30% of the 206 operations.

Aside from the personal consequences of not reporting blood exposures or sharps injuries (personnel are required by law to do so now), hospitals too are imperiled. Left unchecked, a disease-carrying health care worker not only poses a significant liability risk, but also financial risk from postexposure treatment costs, experts say.

In a five-year study published in 1991 in the Annals of Emergency Medicine, researchers found that only 35% of 643 exposure incidents in hospital emergency rooms involved in the study were formally reported. Researchers theorized the reasons for the underreporting included a low perception of risk, many years of prior exposure and concern about excessive paperwork.

'Vast underreporting'

Although no such formal study on the OR has been conducted to date, several officials contacted by OR Purchasing News said the problem is just as severe, if not worse, in the surgical suite.

"There is vast underreporting of exposures in the OR," said Janine Jagger, M.P.H. Ph.D., associate professor of neurosurgery and director of the Healthcare Worker Safety Project at University of Virginia. Jagger's pioneering research in blood exposures was the subject of three nationally published studies in leading journals and forms the foundation of a new exposure reporting and analytical software program marketed by Becton Dickinson. (See related story on p. \$15.)

After three years of research on the subject, Jagger maintains that underreporting of blood exposures is most prevalent in the OR.

To prove her point, Jagger looked at exposure incidences at UVA's hospital, a 600-bed facility in Charlottesville, VA.

Of the 529 sharps injuries reported by the facility during a 15-month period, the OR ranked fifth on the list of exposure-prone departments, with 133 incidents. Of that number, surgeons, one of the highest surgical risk groups for sharps injuries, made only 18 reports.

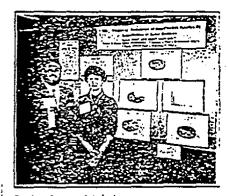
This occurred despite the fact that residents, who are vastly outnumbered by staff physicians, submitted 100 reports of sharps injuries, she said.

In examining blood exposure reports from another facility, Jagger found another startling statistic: Of the 444 reports, 330 involved sharps injuries and only 114 involved blood and body fluid exposures.

"As a general rule, incidences of blee and body fluid contact far outnumbe those of sharps injuries," but in this case they were outnumbered nearly three to-one by sharps injuries, Jagger tol ORPN, "Blood and body fluid contact are very prevalent in the OR, yet the data I'm seeing doesn't even come close to reflecting that."

Jagger said health care workers, in cluding OR personnel, are much les likely to report an incident involving skin contact with blood than a sharps in jury, ostensibly because many believ, the risk of infection is so small.

Moreover, reports involving nonsharps-related blood exposure tend to be the more "shocking," she added, "Many of the reports I see involve a huge amount of blood on a worker's scalp dripping into the eyes, or blood-soaker underwear." Jugger said, "Rarely do I see reports involving drops of blood on a wrist or between a glove and bare hand."



Janine Jagger (right) appears at a recent symposium on needlestick injuries with Murray Cehen, chief, medical devices evaluation for the National Center for Diseases of the Centers for Disease Control and Prevention. Jagger is associate professor of neurosurgery at University of Virginia.

A lifetime of exposur
One New York OR director who asked
to remain anonymous told ORPN that
while her nursing staff is vigilant
about exposures, surgeons are not.

"Surgeons tend to underreport because they have a lifetime of exposure," she said. "If an exposure is reported, it could have a severe economic impact on that surgeon's practice."

The individual added that needlestick injuries, by far the most common type of sharps exposure among OR nurses, often occur when a surgeon "hands back, or in some cases, throws back" a hypodermic needle to a nurse.

Jon Ross, a spokesman for the Chicago-based American Hospital Association, acknowledged that underreporting is commonplace, albeit "unintentional," in most hospital ORs.

"Many people who are exposed have already been exposed and either know of the hazards or don't." Ross said. Some also fear that a test for HIV or HBV-B infection following an exposure incident will come out positive, he added.

"The OR is a fast-paced environment, and unfortunately, many workers assume that exposure to blood goes with the [territory]," Ross said, "A lot of people know what the risk is but are will-

ing to take that risk.

"The issue is not so much one of underreporting as it is the question of what can be done to prevent exposures from happening in the first place," Ross added, saying that the AHA has a comprehensive educational program in place to address the need for more awareness."

Added Jagger, "Health care workers have been given such a high expectation of the number of times they will be

exposed to (infectious) materials that it is so routine to them."

Failure to report an exposure not only poses a threat to one's health, but also to one's economic future, Jagger added. "If a disease is contracted and no report is made, that individual is up the creek in terms of worker's compensation," Jagger said.

Despite the suspected high level of underreporting among surgeons, Jagger

said she sees a promising trend among younger doctors, particularly residents. "We're sceing a tremendous increase in the number of residents who report injuries incurred in the OR," Jagger said. "It's a psychological phenomenon. There's a tremendous amount of concern among newer [health care] professionals. They're learning [to report all exposures] in spite of what they see older sur-

geons doing."

Post-exposure management costs, or those incurred by a facility as a result of an exposure report, can vary widely, according to Greg Sutton, senior product manager for Becton Dickinson's Hypodermic Division.

The cost components include treatment, prophylaxis and lost personnel time.

Sutton said B-D's research shows that the average post-exposure management cost for a sharps injury is \$600; some hospitals have reported spending twice that much on one incident alone, he said.

But Jagger's estimates are more conservative.

In 1990, Jagger co-authored a study in

Infection Control Hospital Epidemiology which concluded, among other things, that the average cost of a needlestick injury was \$405. Jagger also concluded that on average, needlestick injuries account for 36% of the cost of the offending device.

The study was designed to determine whether the savings from prevented needlesticks offset the increased expense of new, safer devices. D



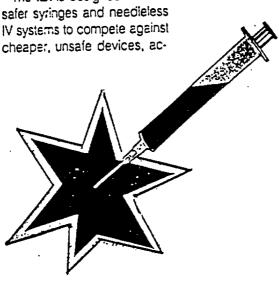


CAPITOL HILL BILL TAKES AIM AT DEADLY NEEDLESTICKS

Legislation designed to induce health-care facilities to use safer needle devices has been introduced in Congress. The proposed law requires the Food and Drug Administration to develop safety standards for syringes and intravenous equipment. The bill also imposes an excise tax, beginning in 1997, on the purchase of items that don't meet the new FDA standards.

The tax is designed to allow

cording to the bill's sponsor. California Congressman Pete Stark. "I hope that this tax bill will never raise a dime," he said. "This-is to provide the price encouragement to do the right thing-provide a safer working environment for our nation's caregivers."



JULY 1993 RN 17

Case 3:96-cv-01187-J-CGA Docperone for the stark Case 3:96-cv-01187-J-CGA Docperone for the stark COMMITTEE ON WAYS AND ME SUBCOMMITTEE ON SELECT REVENUE MEASURES

June 29, 1993

Mr. Chairman, Members of the Committee: I want to thank you for the opportunity to appear before you and provide testimony on two legislative items under consideration, a tax on unsafe needles and support of charitable risk pools.

Anti-Needlestick Legislation

H.R. 1304, legislation Chairman Rangel and I introduced earlier this year, is designed to reduce the risks to health care workers from accidental needlesticks. H.R. 1304 will ensure that the necessary tools -- better information and better medical devices -- are made available to our front-line health care workers in order to reduce the injury and death that has resulted from needlesticks.

I would like to enter into the record a list of some of the individuals, organizations and corporations in support of this legislation. Support for H.R. 1304 has come from all quarters: inventors and manufacturers -- well over a dozen corporations are listed in support -- researchers, and most importantly consumers. They share the opinion that this legislation will facilitate the incorporation of safer needle devices into the workplace.

It is estimated that last year alone there were 800,000 accidental needlesticks in hospital settings from needle-bearing devices. Accidental needlesticks produce the single greatest risk of blood exposure to the HIV virus for health care workers. According to a study by the Centers for Disease Control, 80% of the blood exposures to HIV in the health care setting were caused by needlestick injuries. The CDC has documented at least 36 cases of HIV infection as a result of an accidental needlestick. Infection with the hepatitis B virus and other infectious agents are also transmitted through needlesticks.

Nurses have suffered the greatest number and the greatest harm from accidental needlesticks. Seventeen nurses are known to have contracted HIV from accidental needlesticks. For these reasons, it is not surprising to note that the 200,000-member American Nurses Association, the American Association of Occupational Health Nurses and the Association of Operating Room Nurses have strongly endorsed H.R. 1304.

But nurses are by no means the only ones at risk from accidental needlesticks. Clinical laboratory personnel, fire fighters, patient attendants, housekeeping personnel, and family care-givers are some of the others at tremendous risk from the split second jab of a contaminated needle. This is why the Service Employees International Union has been working for so many years to achieve the measures contained in H.R. 1304, and why they support this legislation. This is why the American Society for Medical Technology representing 20,000 plus non-physician laboratory personnel, the International Association of Firefighters, and the Hospital and Health Care Workers Union all assisted in the drafting of this legislation and have issued statements of support for H.R. 1304.

Imagine what someone must go through when accidentally pricked with a used needle device. Tests must be conducted to determine if the blood on the device contained an infectious agent. If so, the health care worker must undergo tests to see if they have been infected. If the blood contained the HIV virus, one could

not be sure for up to three months whether an infection occurred. With the tremendous number of needlesticks that occur, this process is repeated literally thousands of times each day.

Better information and better devices are the key to reducing injuries from needlesticks. In H.R. 1304, it is recognized that today the greatest tool we can put in the hands of nurses and other health care workers is information. There are dozens and dozens of so-called "safer" needle products on the market and in development. Each of these contains a manufacturer's claim to the efficacy of the device. Some in fact may be safer; others may not. If injuries are to be reduced, better information must be collected as to which medical devices will actually reduce the number of accidental needlesticks.

To compile the information needed, H.R. 1304 requires that the Food and Drug Administration develop safety performance standards for needle devices and subsequently assess the devices to determine whether they have been shown to reduce accidental needlesticks. The FDA is instructed to draw upon the experiences in the private sector with the development of performance criteria and with product assessment. With the assessments in hand, the purchasers and the consumers will then have the information necessary to make their purchase and use decisions. Because these assessments have not yet been conducted to the extent one would have liked, a period of three years is provided for these assessments to take place.

Once this information is in hand, we must ensure that it is used — we must ensure that the better devices get into the workplace. Health care institutions must be encouraged to substitute existing needlestick products with products proven to be safer. To this end, a tax will be imposed three years out — in 1997 — on needle devices not found to reduce the risk of accidental needlesticks. (The tax would be 10 cents per device and would only apply upon sale of needlebearing medical devices to those with Medicare provider numbers. Sales of needles for personal use would not be taxed.)

I'd like to briefly explain how I anticipate the assessment of needle devices to occur. As stated, the FDA would be required to develop safety performance standards. Items such as whether they can be operated with one hand, whether they provide passive protection, whether they prevent reuse, and other considerations deemed appropriate would be listed. Over the first three years, as data becomes available on various products, the devices would be measured against the performance criteria. By 1996, the FDA would make a determination as to the level of performance considered acceptable (i.e. how many of the criteria must be met) for a product to be considered "safer." Due to the limitations of the technology or the cost of production, products might not initially achieve universal compliance with the safety performance standards. Nonetheless, a determination will be made as to what minimum level of performance would be acceptable.

In subsequent years, the level of performance considered acceptable would be raised as technologies improved. To provide purchasers and consumers with the most accurate information possible, product assessments would be updated at least annually by the government.

This approach was chosen after consultations with numerous individuals and groups that manufacture and use medical devices. Many manufacturers and union representatives have been frustrated in their attempts to get safer needle products into the hands of clinicians. Management of health care institutions often respond that the "safer" products are too expensive. A typical straight needle device used today costs a few cents. Needles with the most promising safety features -- while expected to be priced somewhere in the area of 13 to 16 cents when levels of production are sufficiently high -- currently cost several

times the amount of standard needles. A hospital purchasing clerk, looking only to the price of the item, sees a significant price differential. H.R. 1304 would eliminate much of the price differential so that consideration is also given to safety of these products, not just to the price.

If the supply clerk were able to see the entire cost associated with the use of a needle device (the S600 per needlestick for testing and counseling, the trauma of uncertainty, and the loss of health and life), the balance would be more than tipped in the favor of safer products.

There has been some discussion as to whether a tax is an appropriate approach. Mr. Chairman, if I could, I'd ban all needle devices today that didn't provide our front-line health care workers with the best protection available. Forget about imposing a ten cent tax; ban all needle-bearing devices from the workplace that don't provide an adequate level of protection. The problem is that we do not know today which products we would ban and which we would use. Claims are made by manufacturers, and guesses can be offered by those purchasing the products as to the efficacy of the devices, but adequate data on which products actually result in reduced needlesticks has not been compiled.

This legislation ensures that coordinated assessments of these products will take place and that performance as well as cost will be considered in purchase decisions. This legislation sends a clear signal to government and private institutions alike that the status quo is not acceptable. The challenge given to federal agencies such as the FDA is that assessments of product performance must be completed by January 1, 1997. Likewise, this legislation gives health care institutions a target date to incorporate safer needle-bearing devices.

For the sake of the thousands of health care workers on the front-lines of caregiving, for the fire fighters, sanitation workers and laboratory personnel who are at risk from needlesticks, I wish I could tell them that safer medical devices will be available when they report to work tomorrow. Sadly enough, I can't. But through this legislation, by the continued work of government scientists and regulators, with the continued inventive energies of private sector researchers and manufacturers, and through the persistence of union members and representatives to get these devices into the hands of the health care professionals, I believe the workplace will become a much safer place. TO:

Andy Bluhm

DATE:

October 21, 1994

FROM:

Matt Mazur

RE:

Sept. F/S & YTD Shipments

Pursuant to your request, please find a September 30 Balance Sheet as well as a short paragraph regarding shipped product year to date.

The Company has shipped approximately 2,000,000 syringes year to date. Early in the first quarter the Company made a decision to wait until discounts associated with large volumes allow the Company to make gross margins in excess of 50%. This entailed high cavity molds coming on line to produce volumes in excess of 3 million units a month. The Board believed shipping every syringe at a loss for the last six months would have spent too much of the Company's working capital. The Board was right. In August the Company realized a \$0.063 per unit discount from what it had previously been paying for the same assembly labor charges in Mexico. The Company is on pace to produce and sell 15 million units for the fourth quarter and is within 30-60 days of next year's budget.

As you are aware, the Company began selling its Series E Preferred stock October 1, and has raised \$4.5 million dollars or approximately one-third of the entire Series E shares. I would recommend scheduling some time to discuss the Company's Stock Purchase Agreement, who it is that is interested investing, appropriate Blue Sky considerations, timing and any other outstanding issues.

P.S. I would also like a copy of Mr. Engel's write-up.

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/US Medical Instruments, 1. .. Balance Sheet (in Dollars)

September 30, 1994

	_		
LIABILITIES	ΔND	STOCKHOLDERS?	EQUITY.

LIABILITIES AND STOCKHOL	DERS' EQUITY	•
Liabilities		
Current Liabilities:		
Accounts payable	910,414	
Ca sales tax payable	(1,352)	
Payroll taxes payable	(72)	
401K payable	3,947	
Accrued expenses	65,793	
Accrued payroll	34,943	
Accrued vacation	21,391	
Accrued worker comp insurance	1,164	
Notes payable-current	146,700	
Discount on notes payable-current	(18,700)	
Capital lease payable-current	146,588	,
Total Current Liabilities		1,331,185
Long-term Debt:		
Deferred rent payable	64,365	
Discount on notes payable-noncurrent	(54,800)	
Capital lease payable-noncurrent	(1,984)	
Capital lease payable-Textron 1	49,825	
Capital lease payable-Textron 2	37,597	
Capital lease payable-Ellison	45,892	
Capital lease payable-Mitsu EDM	192,058	
Capital lease payable-GE Capital	18, 251	
Capital lease payable-IBM	181,117	
Capital lease payable-Dataworks	41,951	
Less current portion above	(293, 698)	
Total Long-term Debt		280,594
Total Liabilities		1,611,779
Stockholders' Equity:		
Series A Preferred stock	26,640	
Series B Preferred stock	1,636,310	
Series C Preferred stock	576,612	
Series D Preferred stock	10,249,868	
Series E Preferred stock	2,428,415	
Common stock	381,677	
Additional paid in capital	179,818	
Retained earnings	(8,356,876)	
Total Stockholders' Equity		7,122,463
TOTAL LIABILITIES AND		
STOCKHOLDERS' EQUITY		8,734,242
	•	

Case 3:96-cv-01187-J-CGA Document 16 Filed 20/28/96 Page 158 of 212

US Medical Instruments, I. ... Balance Cheet (in Dollars)

September 30, 1994

_ass		ASSETS	
Current	Assets: Cash-Checking Petty cash Accounts receivable	1,637,359 200 783)
	Other receivables Raw materials Work in process	613 121,283 208,913	•
	WIP conversion cost applied Finished goods FGI conversion cost applied	130,841 59,400 31,550	3
	Inventory Reserve Prepaid insurance Other current assets	(8,550 1,960 15,000	7
	Total Current Assets	AL A	2,199,374
Freperty	/, Flant & Equipment: Machinery/equipment Injection molds Leasehold improvements Computer System Office equipment Trade show booth and equipment Less: Accumulated depreciation	2,474,72 805,79 549,48 268,59 123,83 4,86 4,227,29 (236,19	2 5 9 1 5
	Net Property, Plant & Equipmen	 t	3,991,100
Other A	ssets: Patents/licenses Accumulated amortization	368,78 (192,50	
	Deposits	216,27 2,327,49	
	Total Other Assets		2,543,769
	TOTAL ASSETS		8,734,242

EXHIBIT 3 -160-



(a development stage enterprise)
Report and Financial Statements
January 31, 1995

750 B Stres. Scite 2400 San Diego, CA 92101

Telegnone 519 231 1200

Price Waterhouse LLP



Report of Independent Accountants

April 28, 1995, except for the issuance of the convertible secured notes, the legal filing and note payments described in Note 11, as to which the date is September 22, 1995

To the Board of Directors and Shareholders of U.S. Medical Instruments, Inc.

In our opinion, the accompanying balance sheet and the related statements of operations, of shareholders' equity and of cash flows present fairly, in all material respects, the financial position of U.S. Medical Instruments, Inc. (a development stage enterprise) at January 31, 1995 and 1994, and the results of its operations and its cash flows for the years ended January 31, 1995 and 1994 and the period from June 19, 1991 (inception) to January 31, 1995, in conformity with generally accepted accounting principles. These financial statements are the responsibility of the Company's management; our responsibility is to express an opinion on these financial statements based on our audits. We conducted our audits of these statements in accordance with generally accepted auditing standards which require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for the opinion expressed above.

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the financial statements, the Company has incurred development stage losses and has a deficit accumulated during the development stage that raise substantial doubt about its ability to continue as a going concern. In addition, the Company is currently negotiating revised and extended payment terms on certain promissory notes as described in Note 11. Management's plans in regard to these matters are also described in Notes 1 and 11. The financial statements do not include any adjustments that might result from the outcome of these uncertainties.

Price Watshause LLP

(a development stage enterprise)

Balance Sheet

(in thousands, except share amounts)

	Jan	uary 31,
	1995	1994
Assets		
Current assets:		
Accounts receivable		5 2
Inventories	\$ 1,723 21	
Prepaid expenses		
Total current assets	1,744	9
Property and equipment, net - secured (Note 5)	8,108	2,479
Intangible assets, net	1 673	
Other assets	89	69
	<u>\$ 11 614</u>	\$ 2.791
Liabilities and Shareholders' Equity		
Current fiabilities:		
Accounts payable and accrued expenses	\$ 1,198	s 509
Short-term related party notes payable	5 1,100	293
Current portion of long-term notes payable and liabilities to		
related party and others	972	==
Current portion of capital leases Accrued payroll costs	12 6 70	=
Accroed payrox costs		
Total current liabilities	2,366	1,051
Long-term (iabilities:		
Long-term notes payable and liabilities to related party and others	1,159	-
Capital leases, less current portion Deferred rent	352	_
Desailed terif	88	17
Total liabilities	3,965	1 765
Shareholders' equity:		
Preferred stock, 12,000,000 shares authorized;		
5,398,681 and 2,911,337 shares issued and outstanding at January 31, 1995 and 1994, respectively		
Series A Convertible Preferred Stock	26	26
Series B Convertible Preferred Stock	1,636	 -
Series C Convertible Preferred Stock	577	
Series D Convertible Preferred Stock	9,398	
Series E Convertible Preferred Stock Common Stock, no par value; 28,000,000 shares authorized,	9,254	
1,686,832 and 1,617,532 issued and outstanding		
at January 31, 1995 and 1994, respectively	458	382
Additional pard-in capital	1,159	100
Shareholder receivable	(1,705	
Delicit accumulated during development stage	(13.164) (5.682)
Total shareholders' equity	7.649	1,026
Commitments and contingencies (Note 7)		
	\$ 11 614	\$ 2.791

The accompanying notes are an integral part of these financial statements

(a development stage enterprise)

Statement of Operations

(in thousands)

		ar ended buary 31, 1994	Period from June 19, 1991 (inception) to January 31, 1995
Net sales	<u>\$</u> 44	. \$ 1	<u>\$ 50</u>
Costs and expenses: Manufacturing and start-up costs General and administrative Selling and marketing Research and development Total costs and expenses	3,926 1,217 1,136 857	1,049 385 1,116	4,918 3,059 2,092 2,680
Loss from operations	(7,092	(3.175)	(12,699)
Interest and other expense	390	67	465
Net loss	5 (7.482)	\$ (3.242)	\$ (13,164)

The accompanying notes are an integral part of these financial statements.

... Case 3:96-cv-01187-3-CGA - Document 16 Filed: 10/28/96 Page 163 of 212

U.S. Medical Instruments, Inc.

(a development stage enterprise)

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Statement of Shareholders' Equity														
(in thousands, except share amounts)						;		444	Commercial	i		,	Accuratelad	Į
	1	1	Constitute Series A Preterred Sleet	Sarker Sarker Preferred	15	Committee Series C Frehmel Sleck Shares America	'ज । ड	Series D Freferred Siles)	Scries E Projected Shelt Shares Ann	15	Shareholder	Additional Taldita Caphil	detekt turg detrippmen ringe	e i
		Ţ												
Issuance of common stock for certain	552000 \$	474												
assels and costs of founders														
issuance of continuou stock for CAST.	48,000	304											•	(600)
August 1991 to aboutery 1991.														46.0
Net loss for the period non-seriod 1992 1991 (inception) to Jenuary 31, 1992					 									3
Balance at British 31, 1992	600,000	778												
Issuance of common stock for cash,	000	727												
February 1992 to June 1992	057.60	į												
Issuance of common slock for cash,	42,972	603												
June 1992 to July 1992														
Issuance of continues according to the continues of \$37.	!												٦	9
Annual 1992 to January 1993	69,843) (a)		ļ	1	!							ŭ	(2,440)
Net loss for the year ended January 31, 1993														
1007	782,045	4,025												
	3,128,180		92.000	554 195	\$ 1.164 20	205,933 \$	\$ 577 349,895	95 \$ 1,959	_					
Five for one stook state into preferred stock	(2,442,023)	(3,726)	, e vou, 255, 1 (327, c)											
		=												
	20,239	•					. 60	2500	-					
Issuance of Series D preferred for cash April 1993							409,51		1					
	35.466	8												
_														
	10,714	φ	•										90	•
	115,911	46												(3.24)
Exercise of stock options and writtens							 					-)	(5,683)
							000 010	900 4 459	6			_	2	o naci
	1 617.532	382	1,332,000	26 554,195	1,164	205,933			ļ					
Balance at January 31, 1994					473									
×	59,144	20		000,622	<u>.</u>				,					
Report of Series () preferred, net of related							611	ei.	323					
	990 00						921	170,061	3			•	•	
Sale of Series Dipreferred with common slock	3	•					142	142.857 B	900			-	201	
v:							ch	9,378	53					
Control party rice payment							,		CEE 300	5 62 197				
Sales of Series E preferred, net of related									rc'067		\$(1,705)	æ		
										~	(52)	-	7 5	
									1,066,668	iB 7,142	7	-	202	(7.482)
Issuance of warrants to tribute a security										,		١,	-	(1.3 (6.4)
						1200	6577 1716	1718553 \$9,398	1,353,000	20 20 El	202 202 203 203 203 203 203 203 203 203	4	지	
	1,685,832	458	1,332,000	\$ 26 779 195			` ;	1	•					
	:::1			•	1									

The eccompanying notes are an integral part of these financial statements.

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(a development stage enterprise)

Statement of Cash Flows

(in thousands)

		anded ery 31, 1994	Period from June 19, 1991 (inception) to January 31, 1995
Cash flows from operating activities.			
Net loss Adjustments to reconcile net loss to net cash used in operating activities:	\$ (7,482)	\$ (3,242)	\$ (13,164)
Depreciation of property and equipment Amortization of intangible assets	484 58	208 120	802 190
Amortization of discount on notes payable Non-cash charge for equity transaction Non-cash portion of loss on settlement of	20 34	6 11	26 45
related party notes payable Common stock issued for research and development	94		94 322
Common stock issued for services performed Common stock issued for preoperating costs increase (decrease) in cash resulting from changes in:		6	6 97
Accounts receivable Inventories	(1.723)	1 28	(1,723)
Prepaid expenses Other assets Accounts payable and accrued expenses	(14) (20) 689	(7) (13) 269	(26) (83) 1.198
Accrued payroll costs Deferred rent	(41) 71	113	72 88
Net cash used in operating activities	(7,828)	(2,483)	(12,056)
Cash flows from investing activities:			
Payments for property and equipment Payments for intangible assets	(4,545) (750)	(498) (9)	(5,200) (1,085)
Net cash used in investing activities	(5,296)	(507)	(7.285)
Cash flows from financing activities: Net proceeds from issuance of preferred and common stock	12.315	2.566	18.432
Net proceeds from issuance of warrants and other Payments on capital leases	858 (49)	100	958 (49)
Net cash provided by financing activities	13 124	2,555	19 341
Decrease in cash Cash at beginning of period	*	(324) 324	<u> </u>
Cash at end of period	<u> </u>	<u>s</u> .	<u> </u>

The accompanying notes are an integral part of these financial statements.

(a development stage enterprise)

Notes to Financial Statements

NOTE 1 - THE COMPANY AND ITS CAPITAL RESOURCES

U.S. Medical Instruments, Inc. (the "Company") was incorporated in California on June 19, 1991. The Company's business is to design, manufacture and distribute safety medical equipment. The Company's initial product is a safety syringe which the Company plans to market to hospitals and medical product buying groups throughout the United States and worldwide.

The Company incurred net losses of \$7,482,000 and \$3,242,000 for the years ended January 31, 1995 and 1994, respectively, and has a deficit accumulated during the development stage of \$13,164,000 at January 31, 1995. From February 1, 1995 through April 28,1995, the Company has raised \$204,500 through additional equity financing. The Company is currently seeking additional debt and/or equity financing in order to meet its ongoing working capital requirements and to purchase additional capital equipment. Such financing is required for the Company to execute its business plan which contemplates the acquisition of additional equipment, the ramp-up of production and sales of its initial products during the year ending January 31, 1996. Management believes they will be successful in obtaining such financing and achieving their business plan; however, if they are not, there is substantial doubt about the Company's ability to recover its investment in inventories, property and equipment and patented technology, as well as its ability to continue as a going concern.

NOTE 2 - SIGNIFICANT ACCOUNTING POLICIES

inventories

Inventories are valued at the lower of cost (determined by the first-in, first-out method) or market.

Property and Equipment

Property and equipment is recorded at cost and depreciated using the straight-line method over estimated useful tives of three to ten years. Expenditures which substantially increase value or extend useful tives are capitalized. Maintenance and repairs are expensed as incurred. Leasehold improvements are capitalized and amortized over the remaining lease term.

intengible Assets

Intangible assets are recorded at cost and amortized using the straight-line method over their estimated remaining useful lives, which currently range from ten to twelve years.

Revenue Recognition

Revenue from product sales is recognized upon shipment, net of an allowance for sales returns.

Research and Development

Research and development costs are expensed as incurred.

(a development stage enterprise)

Notes to Financial Statements

Income Taxes

Effective February 1993, the Company adopted Statement of Financial Accounting Standards No. 109 (FAS 109). Accounting for Income Taxes. The adoption of FAS 109 changes the Company's method of accounting for income taxes from the deferred method (APB 11) to an asset and liability approach. The asset and liability approach requires the recognition of deferred tax liabilities and assets for the expected future tax consequences of temporary differences between the carrying amounts and the tax bases of other assets and liabilities. The adoption of FAS 109 has no effect on the previously reported results of operations or financial position and the net loss for the year ended January 31, 1994.

Reclassifications

Certain prior year amounts have been reclassified to conform with the current year presentation.

NOTE 3 - COMPOSITION OF CERTAIN FINANCIAL STATEMENT CAPTIONS

Intangible assets: Patents and license agreement Accumulated amortization \$ 1,863 \$ 366 (190) (132) \$ 1,673 \$ 234 Accounts payable and accrued expenses:	MOTE 2 - COURT OUTSTAND A STANDARD OF THE STAN		Janua		
Name Name					
Raw materials S 1,035 Work-in-process 128 560			(in the	pusano	is)
Work-in-process 128 Finished goods 560 S 1.723 Property and equipment, secured (Note 5): \$ 1,723 Machinery \$ 4,132 \$ 623 Injection molds 1,918 534 Leasehold improvements 666 135 Office and computer equipment 404 72 Equipment deposits (Note 7) 1,664 1,433 Accoumulated depreciation and amortization (676) (318) Intangible assets: Patents and license agreement \$ 1,863 \$ 366 Accountly amortization (190) (132) Accounts payable and accrued expenses: 421 132 Accounts payable and accrued expenses: 421 132 Accounts payable and occrued expenses: 421 132 Bank overdrafts 189 51 Accrued advertising 109 6 Other 6 6	1		4.005		
Finished goods 560 S 1.723 Property and equipment, secured (Note 5): Machinery Injection molds		3			
Property and equipment, secured (Note 5): Machinery \$ 4,132 \$ 623 Injection molds \$ 1,918 \$ 534 Leasehold improvements \$ 666 \$ 135 Office and computer equipment \$ 404 \$ 72 Equipment deposits (Note 7) \$ 1,664 \$ 1,433 Accumulated depreciation and amortization \$ (676) \$ (318) Intangible assets: Patents and license agreement \$ 1,863 \$ 366 Accumulated amortization \$ (190) \$ (132) Accounts payable and accrued expenses: Accounts payable and accrued expenses: Accounts payable \$ 479 \$ 320 Accrued expenses \$ 421 \$ 132 Bank overdrafts \$ 189 \$ 51 Accrued advertising \$ 109 Other					
Property and equipment, secured (Note 5): \$ 4.132 \$ 623 Injection molds 1,918 534 Leasehold improvements 666 135 Office and computer equipment 404 72 Equipment deposits (Note 7) 1,664 1,433 Accumulated depreciation and amortization (676) (318) Intangible assets: \$ 8.108 \$ 2,479 Intangible assets: \$ 1,863 \$ 366 Accumulated amortization (190) (132) Accounts payable and accrued expenses: \$ 479 \$ 320 Accounts payable and accrued expenses: \$ 479 \$ 320 Accrued expenses 421 132 Bank overdrafts 189 51 Accrued advertising 109 6 Other 6 6	Finished goods		360		
Machinery \$ 4.132 \$ 623 Injection molds 1.918 534 Leasehold improvements 666 135 Office and computer equipment 404 72 Equipment deposits (Note 7) 1.664 1.433 Accumulated depreciation and amortization (676) (318) Intangible assets: \$ 8.108 \$ 2.479 Patents and license agreement \$ 1.863 \$ 366 Accountlated amortization (190) (132) Accounts payable and accrued expenses: \$ 479 \$ 320 Accounts payable and accrued expenses: \$ 479 \$ 320 Accrued expenses 421 132 Bank overdrafts 189 51 Accrued advertising 109 6 Other 6		<u>s_</u>	1,723		
Machinery \$ 4,132 \$ 623 Injection molds 1,918 534 Leasehold improvements 666 135 Office and computer equipment 404 72 Equipment deposits (Note 7) 1,664 1,433 Accumulated depreciation and amortization (676) (318) Intangible assets: \$ 8,108 \$ 2,479 Intangible assets: \$ 1,863 \$ 366 Account and license agreement \$ 1,863 \$ 366 Account amortization (190) (132) Accounts payable and accrued expenses: \$ 479 \$ 320 Account apyable and accrued expenses: \$ 479 \$ 320 Accrued expenses 421 132 Bank overdrafts 189 51 Accrued advertising 109 6 Other 6 6	Property and equipment, secured (Note 5):				
Leasehold improvements 666 135 Office and computer equipment 404 72 Equipment deposits (Note 7) 1.664 1.433 Accumulated depreciation and amortization (676) (318) Accumulated depreciation and amortization \$ 8.108 \$ 2.479 Intangible assets: \$ 1.863 \$ 366 Accumulated amortization (190) (132) Accounts payable and accrued expenses: \$ 1.673 \$ 234 Accounts payable and accrued expenses: \$ 479 \$ 320 Accrued expenses 421 132 Bank overdrafts 189 51 Accrued advertising 109 6 Other 6 6		S		\$	
Office and computer equipment 404 72 Equipment deposits (Note 7) 1.664 1.433 B.784 2.797 Accoumulated depreciation and amortization (676) (318) Intangible assets: \$ 8.108 \$ 2.479 Intangible assets: \$ 1.863 \$ 366 Accoumulated amortization (190) (132) Accounts payable and accrued expenses: \$ 1.673 \$ 234 Accounts payable and accrued expenses: 421 132 Accrued expenses 421 132 Bank overdrafts 189 51 Accrued advertising 109 6 Other 6	Injection molds				
Equipment deposits (Note 7) 1,664 1,433 8,784 2,797 Accumulated depreciation and amortization (676) (318) Intangible assets: Patents and license agreement \$ 1,863 \$ 366 Accumulated amortization (190) (132) Accounts payable and accrued expenses: Accounts payable and accrued expenses: Accounts payable \$ 479 \$ 320 Accrued expenses 421 132 Bank overdrafts 189 51 Accrued advertising 0 Other 6	Leasehold improvements				
B.784 2.797 (676) (318)	Office and computer equipment		404		_
Accumulated depreciation and amortization (676) (318) \$ 8.108 \$ 2.479 Intangible assets: Patents and license agreement \$ 1.863 \$ 366 Accumulated amortization (190) (132) Accounts payable and accrued expenses: Accounts payable and accrued expenses: Accounts payable \$ 479 \$ 320 Accrued expenses 421 132 Bank overdrafts 189 51 Accrued advertising 109 Other	Equipment deposits (Note 7)		1,664		1,433
Accumulated depreciation and amortization (676) (318) \$ 8.108 \$ 2.479 Intangible assets: Patents and license agreement \$ 1.863 \$ 366 Accumulated amortization (190) (132) Accounts payable and accrued expenses: Accounts payable and accrued expenses: Accounts payable \$ 479 \$ 320 Accrued expenses 421 132 Bank overdrafts 189 51 Accrued advertising 109 Other			R 784		2.797
Intangible assets: Patents and license agreement \$ 1,863 \$ 366 Accumulated amortization \$ 1,673 \$ 234 Accounts payable and accrued expenses: \$ 479 \$ 320 Accrued expenses 421 132 Bank overdrafts 189 51 Accrued advertising 109 6	Accumulated depreciation and amortization		• -		
Patents and license agreement \$ 1,863 \$ 366 Accountlated amortization \$ 1,673 \$ 234 Accounts payable and accrued expenses: \$ 479 \$ 320 Accrued expenses 421 132 Bank overdrafts 189 51 Accrued advertising 109 6		5	8.108	5	2.479
Accumulated amortization (190) (132) \$ 1.673 \$ 234 Accounts payable and accrued expenses: \$ 479 \$ 320 Accrued expenses 421 132 Bank overdrafts 189 51 Accrued advertising 109 6	Intangible assets:				
Accounts payable and accrued expenses: Accounts payable Accrued expenses Accrued expenses Bank overdrafts Accrued advertising Other S 1.673 S 234 A79 S 320 421 132 189 51 Accrued advertising 6	Patents and license agreement	S		5	
Accounts payable and accrued expenses: Accounts payable Accrued expenses 421 132 Bank overdrafts 189 51 Accrued advertising Other 6	Accumulated amortization		(190)		(132)
Accounts payable \$ 479 \$ 320 Accrued expenses 421 132 Bank overdrafts 189 51 Accrued advertising 109 Other 6		<u>s</u>	1,673	<u>s</u>	234
Accrued expenses 421 132 Bank overdrafts 189 51 Accrued advertising 109 Other 6	Accounts payable and accrued expenses:				
Bank overdrafts 189 51 Accrued advertising 109 Other6	Accounts payable	\$		\$	
Accrued advertising 109 Other6	Accrued expenses		421		
Other6	Bank overdrafts				51
	Accrued advertising		109		
\$ 1.198 \$ 509	Other	_			6
		<u>s</u>	1,198	\$	509

(a development stage enterprise)

Notes to Financial Statements

During the year ended January 31, 1993, the Company paid \$250,000 to acquire the exclusive long-term license to certain patents, technical data and trade styles relating to its safety syringe. During the year ended January 31, 1994, the Company paid \$50,000 in minimum royalties related to this agreement. In December 1994, the Company exercised its option under the agreement to pay the royalty obligation in full by paying \$750,000 in December 1994 and agreeing to make 4 semi annual payments of \$212,500 each beginning on June 30, 1995. The Company has capitalized \$1,496,000 representing the present value of all future payments under the agreement, using an effective interest rate of 10%, and is amortizing such costs over the remaining ten year life of the patent.

NOTE 4 - INCOME TAXES

No current or deferred tax provision was necessary for 1995 and 1994 due to net losses of the Company.

Deferred tax assets (liabilities) at January 31, 1995 and 1994 are comprised of the following:

		Janua	ry 31,	*
Description		1995		1994
neac, (butan		(in thou	sanas)
Net operating loss carryforwards	\$	3,990	\$	912
Research and development costs capitalized for tax purposes		1,177		815
Start-up costs capitalized for tax purposes		435		580
Research tax credits		216		152
Depreciation		(514)		(40)
Other		174		59
		5,478		2,478
Deferred tax asset valuation allowance	 -	(5.478)		(2,478)
Net .	<u>s</u>	<u></u>	<u>s</u>	

As of January 31, 1995, the Company has Federal and state net operating loss carryforwards of approximately \$10,063,000 and \$5,030,000, respectively. The Federal and state net operating loss carryforwards expire beginning in 2008 and 1998, respectively. The Company also has research credit carryforwards for Federal and state tax reporting purposes totaling approximately \$138,000 and \$78,000, respectively, which expire at various times through 2009. As there can be no assurance that the deferred tax asset will be realized, a full valuation allowance has been provided.

As of January 31, 1995, the Company believes that it has incurred an ownership change pursuant to Section 382 of the Internal Revenue Code and, as a result, the Company believes that its ability to utilize its current net operating loss and credit carryforwards, and realize the benefit of future tax deductions in subsequent periods will be subject to annual limitations.

(a development stage enterprise)

Notes to Financial Statements

NOTE 5 - LONG-TERM NOTES PAYABLE AND LIABILITIES TO RELATED PARTIES AND OTHERS

At January 31, 1995 and 1994, the Company had long-term notes payable and liabilities outstanding as follows.

		1995 (in thou	1994 usands)
Secured promissory note, 60 monthly payments of \$12,750 with 5.8% interest per annum, balloon payment of \$411,940 due February 1999; secured by certain manufacturing equipment	\$	870	
Secured promissory note, 12 monthly payments of \$14,729 with 1.9% interest per annum; balloon payment of \$347,155; due December 28, 1995; secured by certain manufacturing equipment		515	
Long-term liability on patent, 4 payments of \$212,500 beginning on June 30, 1995 and due each six month period thereafter ending December 31, 1996, which have been discounted to their net present value using an effective interest rate of 10% (Note 3)		746	
Secured promissory note due to a shareholder, 60 monthly payments of \$18,100 with 8 percent interest per annum, maturing October 29, 1998; secured by certain manufacturing equipment (net of discount of \$86,000). Note was settled August 5,1994			\$ 778
Less current portion		2,131 (972)	778 (136)
	<u>\$</u>	1.159	\$ 642
The obligations are payable as follows for the years ending January 31 (in t	housan	ds),	
1996 1997 1998 1999 2000	\$	972 506 118 125 410	
	<u>s</u>	2,131	

(a development stage enterprise)

Notes to Financial Statements

On August 5, 1994, the Company had an outstanding promissory note payable to a shareholder with a face value of \$851,000, accrued interest of \$31,000 and an unamortized discount of \$69,000. The note was settled by issuing the shareholder 142,857 shares of Series D preferred stock valued at \$800,000, a warrant to purchase 228,000 shares of common stock at \$.56 per share, and cash of \$82,000. The warrants were valued at \$107,000 The Company recorded a loss on extinguishment of debt of \$176,000 on this transaction (Notes 6 and 8).

HOTE 6 - CERTAIN RELATED PARTY TRANSACTIONS

A shareholder and director of the Company is also a partner in a professional firm providing legal and patent advice to the Company. The Company paid the professional firm approximately \$69,000 and \$47,000 during the years ended January 31, 1995 and 1994, respectively, for legal services. Amounts due to the professional firm tor legal services at January 31, 1995 were \$48,000.

A shareholder and director of the Company provides consulting services to the Company. The Company paid the consultant approximately \$30,000 during the year ended January 31, 1995.

At January 31, 1994, the Company had outstanding short term notes payable to certain shareholders totalling \$293,000 with terms of up to 3 months bearing interest at 7.5 to 8 percent payable in cash or common stock purchase warrants (Note 8). Such notes were paid in full during the year ended January 31, 1995.

The secured promissory note due to a shareholder at January 31, 1994 was issued with detachable stock purchase warrants (Notes 5 and 8). During 1995, the Company exchanged this shareholder note payable for Series D preferred stock, warrants and cash (Notes 5 and 8).

HOTE 7 - COMMITMENTS AND CONTINGENCIES

In September 1993, the Company entered into a lease agreement for its headquarters and manufacturing facility. The term of the lease is five years and commenced January 1, 1994. The agreement provides for options to lease an additional 18,000 square feet at any time before June 1996 and to renew the lease for two consecutive periods of three years each and also contains certain abatement periods. Rent expense is recognized ratably over the lease term. The Company also leases certain manufacturing and computer equipment under operating and capital leases. Rent expense for leased facilities and equipment was \$312,000 and \$79,000 for the years ended January 31, 1995 and 1994, respectively. Capitalized lease amounts included under property and equipment were \$541,000 and \$62,000 as of January 31, 1995 and 1994, respectively, net of accumulated amortization of \$47,000 and \$3,000, respectively.

The Company is subject to certain claims and disputes arising in the normal course of its business. The Company believes that the disposition of these matters will not have a material adverse effect on the linancial position of the Company.

(a development stage enterprise)

Notes to Financial Statements

Future minimum lease payments under capital and operating leases are as follows for the year ending January 31, (in thousands):

Years 1996 1997 1998 1999 2000 Total minimum lease payments Amount representing interest		pital eses	Operating Leases		
1996	\$	174	s	195	
1997		163		315	
1998		125		357	
		74		337	
		45		10	
Total minimum lease payments		581	\$	1,214	
Amount representing interest	 -	103		,	
Present value of minimum lease payments	<u>s</u>	478			

During the year ended January 31, 1995, the Company placed purchase orders with suppliers of machinery and equipment totalling \$2,826,000. In conjunction with these orders, the Company has paid deposits of \$1,664,000 which is included in property and equipment and has remaining commitments of \$1,162,000.

The Company has an employee/shareholder agreement with a key employee/shareholder which provides for a maximum of \$540,000 to be paid to the employee/shareholder upon termination of employment.

(a development stage enterprise)

Notes to Financial Statements

NOTE 8 - SHAREHOLDERS' EQUITY

In April 1993, the shareholders approved a five for one stock split and in August 1994 approved an increase in the authorized shares to 12 million preferred shares and 28 million common shares. The stock split resulted in the issuance of 3,128,180 additional shares of common stock from authorized but unissued shares. The following preferred shares are issued and outstanding:

presented and	January 31,				
		1995	•	1994	
		(in thou	sands)	
Series A Convertible Preferred Stock (Series A), \$.002 per annum noncumulative dividend, no par value; 1,332,000 shares authorized,		·			
issued and outstanding at January 31, 1995 and 1994	\$	26	\$	26	
Series B Convertible Preferred Stock (Series B),					
\$.21 per annum noncumulative dividend, no par value; 937,150 shares authorized, 779,195 and 554,195 issued				,	
and outstanding at January 31, 1995 and 1994		1,636		1,164	
Series C Convertible Preferred Stock (Series C).					
\$.28 per annum noncumulative dividend, no par value, 222,020 shares authorized, 205,933 issued					
and outstanding at January 31, 1995 and 1994		577		577	
Series D Convertible Preferred Stock (Series D),					
\$.56 per annum noncumulative dividend.					
no par value, 1,780,000 shares authorized.					
1,718,553 and 819,209 issued and outstanding	_	0.200		4 450	
at January 31, 1995 and 1994	•	9,398		4,459	
Series E Convertible Preferred Stock (Series E)					
5.75 per annum noncumulative dividend, no par					
value, 2,000,000 shares authorized, 1,363,000 issued					
and outstanding at January 31, 1995		9,264			
Total Preferred shares	<u>5</u>	20,901	<u>s</u>	6,226	

In April 1993, the shareholders approved a recapitalization plan whereby the common shareholders converted their common shares into Preferred Series A. Series B. Series C. or Series D. depending on the price originally paid for such common shares. All outstanding shares of Series A and C. 554,195 shares of Series B, and 349,895 shares of Series D were former common shares pursuant to this plan.

(a development stage enterprise)

Notes to Financial Statements

In the event of any liquidation, dissolution or winding up of the Company, the holders of Series A, B, C, D and E In the event of any state of the common preference to any distribution of any assets to the common preferred Stock shall be entitled to receive, prior and in preference to any distribution of any assets to the common preferred Stock shall be entitled to receive, prior and in preference to any distribution of any assets to the common preferred Stock shall be entitled to receive, prior and in preference to any distribution of any assets to the common preferred Stock shall be entitled to receive, prior and in preference to any distribution of any assets to the common preferred Stock shall be entitled to receive, prior and in preference to any distribution of any assets to the common preferred Stock shall be entitled to receive. Preferred Stock an amount per share equal to \$0.02, \$2.10, \$2.80, \$5.60 and \$7.50 plus an amount equal to all shareholders, an amount equal to all declared but unpaid dividends, respectively.

On or after April 30, 1996, the Company may, at the option of the Board of Directors, redeem in whole or in part Union directions, redeem in whole or in part the Series A. B. C. D and E Preferred stock by paying cash equal to the original issue price for each share, plus the Series A. B. C. D and E Preferred stock by paying cash equal to the original issue price for each share, plus any declared but unpaid dividends on such shares.

Each share of Series A, B, C D and E Preferred Stock is initially convertible into one share of Common Stock, at the option of the shareholder, at any time prior to redemption by the Company or automatic conversion. The the option of the subject to adjustment in the event of a stock split or stock dividend. The Preferred Stock has conversion rate in the common stock voting rights, and automatically converts into shares of voting rights which are identical to the common stock voting rights, and automatically converts into shares of voting rights which immediately upon an initial public offering which results in gross proceeds to the Company Common Stock immediately upon an initial public offering which results in gross proceeds to the Company exceeding \$3,000,000.

Warrants

in connection with the issuance of short-term notes payable to directors and shareholders, the Company issued warrants to purchase 81,184 and 17,656 shares of common stock at \$0.56 per share during the years ended warrants to post and 1994 respectively. The warrants were granted at prices equal to the fair market value at the date of grant. Approximately 32,144 warrants were exercised during fiscal year 1995 and the remaining warrants are exercisable at any time through February 2004. The warrants issued in 1995 were valued at \$34,000 and charged to interest expense. The value of the warrants issued in 1994 was considered immaterial.

During fiscal year 1994, in connection with the issuance of a long-term note due to a shareholder, the Company assed warrants to purchase 50,000 shares of Series D Preferred Stock at \$5.60 per share. The warrants may be exercised at anytime through November 1998 (Note 5). The fair values of these warrants have been recorded as a discount to the related debt and charged to expense ratably over the debt repayment terms. In August 1994, the shareholder note was settled in exchange for 142,857 shares of Series D preferred stock valued at \$800,000, a warrant to purchase 228,000 shares of common stock at \$.56 per share, and cash. The warrants were valued at \$107,000 (Note 5).

In connection with the sale of Series E Preferred stock, the Company issued warrants to purchase 213,334 shares of Series E Preferred stock at \$7.50 per share. The proceeds of the issuance were allocated based upon the estimate fair value of the securities issued. Additionally, the Company issued warrants to purchase 18,667 shares of Series E Preferred stock at \$7.50 per share to a third party as payment for a finder's fee for the above transaction. These warrants were valued at \$28,000 and recorded as a financing cost of the sale of Series E preferred stock. All warrants issued in connection with this transaction are exercisable at any time until expiration on January 31, 1998.

Shareholder receivable

At January 31, 1995, the Company had as receivable from a stockholder for \$1,700,000 for the purchase of 226,670 shares of Series E Preferred Stock which was collected in full in February 1995. Additionally, the Company had a receivable from a stockholder for \$5,000 for the purchase of 10,156 shares of common stock.

(a development stage enterprise)

Notes to Financial Statements

NOTE 9 - STOCK OPTION PLAN

During the year ended January 31, 1994, the Board of Directors approved a stock option plan ("the plan") which provides for the granting of options or stock purchase rights to employees, directors and outside consultants of the Company. Nonstatutory stock options and incentive stock options may be granted at an exercise price not less than 85 percent and 100 percent, respectively, of the fair market value of the Common Stock, as determined by the Board of Directors, on the date of grant of such option. At January 31, 1995, options for 489,585 common shares were available for future grant under the Plan and 289,791 were exercisable.

The options granted, exercised and cancelled under this plan during the years ended January 31, 1994 and 1995 were as follows:

	Options Out	Options Outstanding			
	Number of Shares		e per		
Options granted Options exercised	420.000 (105,000)	\$.56 .56		
Balance at January 31, 1994	315,000				
Options granted Options exercised Options cancelled	630,000 (15,000) (139,585)	\$.56 .58 .56		
Balance at January 31, 1995	790,415				

During the year ended January 31, 1993, certain key employees were granted non-statutory options to purchase 292,160 (post-split) shares of Preferred Stock at an exercise price of between \$2.10 to \$5.60 per share. All options were fully vested upon grant, none were exercised and 30,000 were cancelled during the year ended January 31, 1994. During the year ended January 31, 1995, 225,000 were exercised and 37,160 were cancelled. None of these options remain outstanding at January 31, 1995.

During the year ended January 31, 1995, the Company granted options to purchase 72,000 shares of common stock at \$.56 and \$.75 per share to the members of the Board of Directors. The 5.56 per share options vested immediately while the \$.75 per share options vest in equal monthly instalments over a one year period. All options were granted at prices equal to or greater than the fair market value at the date of grant. Approximately 12,000 shares were exercised in November 1994 and 10,000 shares were exercisable at January 31, 1995. The outstanding options expire December 31, 1995.

During fiscal year 1994, in connection with the severance agreement of a director and a former officer of the Company, an option to purchase 22,911 shares of common stock was issued with an exercise price of \$.56 which was exercised during fiscal year 1994. The options were granted at prices equal to the fair market value of the date of grant.

(a development stage enterprise)

Notes to Financial Statements

NOTE 10 - SUPPLEMENTAL CASH FLOW INFORMATION

The Company's payments for interest and income taxes were as follows (in thousands):

January 31,		Period from June 19, 1991 (inception) to January 31,				
	1	1995		994		995
I-11		125	c	60	s	205
Interest paid Income taxes paid	S	135 1	S S	62 1	\$	4
Non-cash investing and financing activities were as follows (in thousands):						
Series D Preferred shares and warrants					_	
issued in settlement of debt (Note 5)	5 S	907	\$	100	=	907 134
Warrants issued in lieu of interest and other (Note 8) Warrants issued in lieu of finders fee on	3	34	3	100	J	134
Preferred shares (Note 8)	\$	28			S	28
Stock issued for finders fee and other	5	75	S	6	\$	81
Common stock issued to founders for: Property and equipment					S	24
intangible assets					S	31
Research and development expense					\$ \$	322 97
Reimbursement of preoperating costs					Ð	31

NOTE 11 - SUBSEQUENT EVENTS

In August 1995, the Company issued two convertible secured notes payable to a shareholder for a total of \$4,000,000 together with warrants to purchase 106,667 shares of Series E preferred stock. The Company received proceeds of \$2,000,000 in August 1995 and expects to receive the remaining \$2,000,000 in September 1995. The notes are due in August 1998 and bear interest at 9% payable quarterly. The notes are secured by the Company's patents, plastic injection molds, and automated assembly equipment. At any time prior to August 1998, the notes are convertible into Series E preferred stock at \$7.50 per share.

The Company has been notified that allegations of a breach of contract for failure to make timely payments on certain promissory notes aggregating \$1,385,000 have been filed in superior court and that the holder of these notes is requesting full repayment thereof. As of September 22, 1995, the Company had paid \$210,000 to the holder of the notes, which includes late amounts, and is currently negotiating both revised and extended payment terms for the notes. Although there can be no assurances, management believes that it will resolve this matter without a material adverse effect on the financial position of the Company.

In April 1995, the Company issued notes payable to certain shareholders totaling \$350,000 together with 42,000 warrants to purchase common stock. The notes were paid as of September 22, 1995 and had interest at 8% per annum. The common stock purchase warrants have an exercise price of \$.75 per share and are exercisable until April 2005.

02/15/96

P 004 2000**2**

Agreement to Extend Date to Sue

By their signatures, the undersigned, on behalf of themselves and those they represent hereby agree to extend to June 30, 1996, the date by which the Medicine Partners may file any claims, suits, or causes of action in whatever form against U.S. Medical, its agents, officers, and directors arising from or relating to the sale and purchase of U.S. Medical's Series E Preferred Stock. The undersigned, Matthew S. Mazur, on behalf of himself and those he represents (U.S. Medical, its agents, officers, and directors) agree they will not raise such issues as statute of limitations, the doctrines of laches, expiration of applicable warranty or representation periods, or other potential time bar in response to an action by The Medicine Partners on or before June 30, 1996. Notwithstanding the foregoing extension, the Medicine Partners agree that it will not initiate any lawsuit prior to May 30, 1996, against U.S. Medical, its agents, officers, and directors arising from or relating to the sale and purchase of U.S. Medical's Series E Preferred Stock. And notwithstanding all of the foregoing, nothing herein shall shorten any applicable statute of limitations for any claims, suits, or causes of action of the Medicine Partners against U.S. Medical, its agents, officers, and directors. The execution of this agreement shall in no way operate as an admission of liability or responsibility by any party hereto or any of their respective affiliates, or constitute a waiver or abandonment of any claim. The parties otherwise retain and reserve all of their rights. By his signature, the undersigned, Matthew S. Mazur represents that he is properly authorized to bind U.S. Medical, its agents, officers, and directors to this Agreement. By his signature, the undersigned, William I. Abrams, represents that he is properly authorized to bind The Medicine Partners, its agents, officers, directors, and partners to this Agreement.

Dated: February 15, 1996

AGREED TO AND ACCEPTED:

Matthew S. Mazur, individually and on behalf of U.S. Medical Instruments, Inc., its agents, officers and directors

Dated: February ____ 1996

William J. Abrams

On behalf of The Medicine Partners

Agreement to Extend Date to Sne

By their timestores, the understand, on behalf of themselves and those they represent bendy serve to extend to June 30, 1896, the date by which G.C. Investments, LLC may file any claims, suits, or causes of action in whotever form against U.S. Medical , its agents, officers, and directors selected from or relating to the sale and prochese of U.S. Medical's Series R Preferred Stock. The understand, Matthew S. Mazur and James R. Yaster, on behalf of themselves and three they received (U.S. Medical its special officers, and directors) sense they will not raise such issues at white of limitations, the decisies of lackes, expiration of applicable warranty or representation periods, or other potential time har in supported to an action by G.C. Investments. LLC car or before June 30, 1996. Notwithstanding the foregoing entersion, G.C. Investments. LLC serve that it will not initiate any lawsuit prior to May 30, 1996, equingt U.S. Modicul, its agents, officers, and firectors arising from or relating to the sale and purchase of U.S. Medical's Series B Preferred Stock. And notablishanding all of the foregoing, nothing herein shall shorten any amplicable statute of limitations by any plaints, salits, or causes of action of G.C. Investments. LLC against U.S. Medical, its agents, officers, and directors. The execution of this percement shall in no way cocatts as an admission of hability or responsibility by any party heads or any of their respective affiliates, or exercitate a waiver or absolutionant of any claim. The parties officerwise retain and reserve all of their rights. By their signatures, the undersioned, Matthew S. Means and James R. Venter represent that they are properly authorized to bind U.S. Medical, its nacras, officers, and directors to this Agreement. By his signature, the undersigned, Ritan Greenstone, represents that he is properly authorized to hind G.C. Investments, II.C. he abents, officers, directors, and partners to this Agreement.

Dated: February 5, 1996

Dated: February 15, 1996

Dated: Pebroary ____, 1996

AGREED TO AND ACCEPTED:

Mathew S. Mann, inflyingly and on behalf of U.S. Missical Instruments, Inc., in goods, officers and directors

Isone R. Yarter, milwidually and

crybehalf of U.S. Metical Instruments, Inc.,

the presents, officers and directors

Belon Greenspub

On belief of G.C. Investment, LLC

Ø1001

Agreement to Extend Date to Sue

By their signatures, the undersigned, on behalf of himself and those he represents hereby agree to extend to June 30, 1996, the date by which the Medicine Partners may file any claims. suits, or causes of action in whatever form spainst U.S. Medical, its agents, officers, and directors arising from or relating to the sale and purchase of U.S. Medical's Series E Preferred Stock. The undersigned, James R. Yarter, on behalf of himself and those he represents (U.S. Medical, its agents, officers, and directors) agree they will not raise such issues as statute of limitations, the doctrines of laches, expiration of applicable warranty or representation periods, or other potential time bar in response to an action by The Medicine Partners on or before June 30, 1996. Notwithstanding the foregoing extension, the Medicine Partners agree that it will not initiate any lawsuit prior to May 30, 1996, against U.S. Medical, its agents, officers, and directors arising from or relating to the sale and purchase of U.S. Medical's Series E Preferred Stock. And notwithstanding all of the foregoing, nothing herein shall shorten any applicable statute of limitations for any claims, suits, or causes of action of the Medicine Partners against U.S. Medical, its agents, officers, and directors. The execution of this agreement shall in no way operate as an admission of liability or responsibility by any party bereto or any of their respective affiliates, or constitute a waiver or abandonment of any claim. The parties otherwise retain and reserve all of their rights. By his signature, the undersigned, James R. Yarter represents that he is properly authorized to bind U.S. Medical, its agents, officers, and directors to this Agreement. By his signature, the undersigned, William J. Abrams, represents that he is properly authorized to bind The Medicine Partners, its agents, officers, directors, and partners to this Agreement.

AGREED TO AND ACCEPTED:

Dated: February /5. 1996

Yarter individually and

ordichaif of U.S/Medical Instruments, Inc.,

its agents, officers and directors

Dated: February /6. 1996

illiam J. Abrams

On behalf of The Medicine Partners

U.S. MEDICAL INSTRUMENTS, INC.

16825 Via del Campo Court San Diego, California 92127

SERIES E PREFERRED STOCK AND WARRANT PURCHASE AGREEMENT

December 16, 1994

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 F Voting Agreement

U.S. MEDICAL INSTRUMENTS, INC.

SERIES E PREFERRED STOCK AND WARRANT PURCHASE AGREEMENT

This Series E Preferred Stock and Warrant Purchase Agreement (the "Agreement") is made as of December 16, 1994, by and between U.S. Medical Instruments, Inc., a California corporation (the "Company") and the Purchaser listed on Schedule 1 hereto (the "Purchaser").

Section 1

Authorization and Sale of Series E Preferred Stock

- 1.1 <u>Authorization</u>. The Company has authorized the sale and issuance of up to Five Hundred Thirty-Three Thousand Three Hundred Thirty-Four (533,334) shares of its Series E Preferred Stock and the issuance of warrants to purchase up to one hundred six thousand six hundred and sixty seven (106,667) shares of the Company's Series E Preferred Stock.
- 1.2 <u>Sale of Series E Preferred</u>. Subject to the terms and conditions of this Agreement, the Purchaser agrees to purchase at the Closing, and the Company agrees to sell to the Purchaser at the Closing, the respective number of shares of the Company's Series E Preferred Stock (the "Series E Shares") listed on Schedule 1 hereto at a per share purchase price of \$7.50. The Purchaser shall pay for the Series E Shares by means of a bank certified or cashier's check or by wire transfer in immediately available funds.
- 1.3 <u>Warrant Agreement</u>. Pursuant to the Warrant To Purchase Shares of Series E Preferred Stock of U.S. Medical Instruments, Inc. (the "Warrant Agreement") by and between the Company and Purchaser, dated December 16, 1994, Purchaser is entitled to acquire from Company, at any time until December 16, 1997 one hundred six thousand six hundred and sixty seven (106,667) Shares of the Company at a price of \$7.50 per share, subject to adjustment ("Warrant Shares").

Section 2

Closing Date: Delivery

2.1 Closing Date. The closing of the purchase and sale of the Series E Shares hereunder (the "Closing") shall be held at the offices of the Company, 16825 Via del Campo Court, San Diego, California 92127 at 10:00 a.m., on December 16, 1994 or at such other time and place upon which the Company and the Purchaser shall agree (the date of the Closing is hereinafter referred to as the "Closing Date").

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2.2 <u>Delivery</u>.

(a) At the Closing, the Company will deliver to the Purchaser certificates, registered in the Purchaser's name, representing the Series E Shares to be purchased. Such delivery shall be against payment of the purchase price therefore.

Section 3

Representations and Warranties of the Company

- 3.1 Organization and Standing: Articles and Bylaws. The Company is a corporation duly organized and existing under, and by virtue of, the laws of the State of California and is in good standing under such laws. The Company has requisite corporate power to own and operate its properties and assets and to carry on its business as presently conducted and as proposed to be conducted. The Company is qualified or licensed as a foreign corporation in all jurisdictions where the nature of its business or property makes such qualification or licensing necessary and where the failure to do so would have a material adverse effect (financial or otherwise) on the business, property, prospects, assets or liabilities of the Company. The Company has, upon request, furnished the Purchaser or its counsel with copies of its Articles of Incorporation and Bylaws. Said copies are true, correct and complete and contain all amendments through the Closing Date.
- 3.2 <u>Corporate Power</u>. The Company will have at the Closing Date all requisite legal and corporate power to execute and deliver this Agreement, to sell and issue the Series E Shares hereunder and to carry out and perform its obligations under the terms of this Agreement.
- 3.3 Authorization. All corporate action on the part of the Company, its directors and shareholders necessary for the authorization, execution, delivery and performance of this Agreement by the Company, the authorization, sale, issuance and delivery of the Series E Shares and the performance of all the Company's obligations hereunder has been taken or will be taken prior to the Closing. This Agreement, when executed and delivered by the Company, shall constitute a valid and binding obligation of the Company enforceable in accordance with its terms, subject to laws of general application relating to bankruptcy, insolvency and the belief of debtors and rules of law governing specific performance, injunctive relief or other equitable remedies. The Series E Shares and the Warrant Shares, when issued in compliance with the provisions of this Agreement and of the Warrant, respectively, will be validly issued and will be fully paid and nonassessable. The Series E Shares and the Warrant and Warrant Shares will be free of any liens or encumbrances other than those created by or imposed upon the holders thereof through no action of the Company; provided, however, that the Series E Shares the Warrant and Warrant Shares may be subject to restrictions on transfer under state and/or federal securities laws as set forth herein.

- 3.4 <u>Capitalization</u>. The authorized capital stock of the Company is, or will be immediately prior to the Closing, 28,000,000 shares of Common Stock of which 1,698,350 are issued and outstanding and 12,000,000 shares of Preferred Stock, of which 1,332,000 shares have been designated as Series A Preferred Stock, 1,332,000 of which are issued and outstanding, 937,150 shares have been designated as Series B Preferred Stock, 779,195 of which are issued and outstanding, 222,020 have been designated as Series C Preferred Stock, 205,933 of which are issued and outstanding, 1,780,000 shares have been designated as Series D Preferred Stock 1,718,553 shares of which are issued and outstanding, and 2,000,000 shares have been designated as Series E Preferred Stock, 694,996 of which are issued and outstanding. All such issued and outstanding shares have been duly authorized and validly issued, are fully paid and nonassessable, and when sold by the Company were issued in compliance with all applicable state and federal laws concerning the issuance of securities. In addition the Company has outstanding options to acquire 290,000 shares of Common Stock that have been reserved for issuance upon the exercise of outstanding warrants. In addition, the Company has reserved an additional 1,300,000 shares of Common Stock for issuance under the Company's 1993 Stock Plan (the "Option Plan") of which approximately 1,010,000 options have been granted. Except for such rights, at the time of the Closing, there will be no other outstanding rights, options, warrants, conversion rights or agreements for the purchase or acquisition from the Company of any shares of its capital stock. Except as set forth in the Investor Rights Agreement entered into between the parties hereto as of the date hereof, no person has any right of first refusal or any preemptive rights in connection with the issuance of the Series E Shares or the Warrant Agreement or the Warrant Shares, or the issuance of Common Stock upon conversion of the Series E Shares.
- 3.5 Financial Statements. The Company has delivered at or prior to the Closing to the Purchaser the Company's audited financial statements for the fiscal years ended January 31, 1994 and 1993 and unaudited financial statements for the period ended June 30, 1994 (the "Financial Statements"). The Financial Statements are complete and correct in all material respects and have been prepared in accordance with generally accepted accounting principles ("GAAP") applied on a basis consistent with prior accounting periods except to the extent that the unaudited financial statements do not contain notes. The Financial Statements present fairly the financial condition and operating results of the Company as of the date and during the periods indicated therein. Except to the extent reflected or reserved against or disclosed in the Financial Statements, the Company as of the date of the Financial Statements had no liabilities or obligations of any kind, whether accrued, absolute, contingent or otherwise, which under generally accepted accounting principles should have been as reflected or reserved against or disclosed.
- 3.6 <u>Litigation</u>. There are no actions, suits, proceedings or investigations pending against or by the Company or its properties before any court or governmental agency (nor, to the best of the Company's knowledge, is there any threat thereof or basis therefor), which, either in any case or in the aggregate, might result in any material adverse change in the business or financial condition of the Company or any of its properties or assets, or in any material impairment of the right

or ability of the Company to carry on its business as now conducted or as proposed to be conducted, or in any material liability on the part of the Company, and none which questions the validity of this Agreement, the Registration Rights Agreement or the Security Agreement or any action taken or to be taken in connection herewith or therewith. The Company is not a party or subject to the provisions of any order, writ, injunction, judgment or decree of any court or governmental agency or instrumentality. There is no action, suit, proceeding or investigation by the Company currently pending or that the Company intends to initiate.

- 3.7 <u>Disclosure</u>. This Agreement, the exhibits hereto, all certificates delivered to the Purchaser pursuant to this Agreement, do not contain any untrue statement of a material fact and when read together do not omit to state a material fact necessary in order to make the statements contained herein and therein not misleading. There is, to the best knowledge of the Company, no fact or currently existing set of circumstances which materially adversely affects the business, prospects, condition, affairs or operations of the Company or any of the Company's properties or assets or materially adversely affects the ability of the Company to perform its obligations under this Agreement which had not been disclosed to the Purchaser.
- 3.8 <u>Changes</u>. Since June 30, 1994, except as contemplated by this Agreement, there has not been:
- (a) any change in the assets, liabilities, prospects, financial condition or operations of the Company from that reflected in the Financial Statements, except changes in the ordinary course of business which have not been, either in any case or in the aggregate, materially adverse;
- (b) any material increase in the outstanding indebtedness owed by the Company;
- (c) any material change in the contingent obligations of the Company by way of guaranty, endorsement, indemnity, warranty or otherwise; or
- (d) any damage, destruction or loss, whether or not covered by insurance, materially and adversely affecting the properties or business of the Company.
- 3.9 Patents, Trademarks, etc. The Company owns or has the right to use, free and clear of all liens, charges, claims and restrictions, all patents, trademarks, service marks, trade names, copyrights, computer software programs, licenses, trade secrets and rights necessary to its business as now conducted or proposed to be conducted and, to the best of its knowledge, is not infringing upon or otherwise acting adversely to the right or claimed right of any person under or with respect to any of the foregoing.

3.10 Compliance with Other Instruments, None Burdensome, etc. Except as disclosed on Schedule 3.10, the Company is not in violation of any term of its Articles of Incorporation or Bylaws, or in any material respect of any term or provision of any mortgage, indenture, contract, agreement, instrument, judgment or decree (whether by cross-default or otherwise), and to the best of its knowledge is not in violation of any order, statute, rule or regulation applicable to the Company. The execution, delivery and performance of, and compliance with, this Agreement and the issuance of the Series E Shares and Warrant have not resulted and will not result in any violation of, or conflict with, or constitute a default under (including in any such case the passage of time or giving of notice or both), any mortgage, indenture, contract, agreement, instrument, judgment, decree, order, statute, rule or regulation applicable to the Company or result in the creation of any mortgage, pledge, lien, encumbrance or charge upon any of the properties or assets of the Company; and there is no such violation or default which materially and adversely affects the business of the Company; and there is no such violation or default which materially and adversely affects the business of the Company or any of its properties or assets.

Section 4

Representations and Warranties of the Purchaser

- 4.1 <u>Representations and Warranties of the Purchaser</u>. The Purchaser hereby represents and warrants to the Company with respect to the purchase of the Series E Shares as follows:
- (a) Experience. The Purchaser has substantial experience in evaluating and investing in private placement transactions so that it is capable of evaluating the merits and risks of investment in the Company. The Purchaser, by reason of his business or financial experience, or the business or financial experience of its professional advisors who are unaffiliated with and who are not compensated by the Company, or any affiliate or selling agent of the Company, directly or indirectly, has the capacity to protect its own interest in connection with the purchase of the Series E Shares hereunder.
- (b) Accredited Investor. The Purchaser (i) has an individual net worth, or joint net worth with Purchaser's spouse, in excess of \$1,000,000, or (ii) has an individual income in excess of \$200,000, or joint income with Purchaser's spouse, in excess of \$300,000 in each of the two most recent years and has a reasonable expectation of reaching the same income level in the current year, or (iii) is a corporation, Massachusetts or similar business trust or partnership, not formed for the specific purpose of acquiring the Series E Shares, with total assets in excess of \$5,000,000, or (iv) is a trust not formed for the specific purpose of acquiring the Series E Shares, which purchase of the Series E Shares is directed by a person with such knowledge and experience in financial and business matters such that he is

capable of evaluating the merits and risks of the perspective investment, and the trust has total assets in excess of \$5,000,000.

(c) <u>Risk</u>. The Purchaser understands and acknowledges that there are many risks associated with the purchase of the Series E Shares, including, but not limited to, the following:

The Purchaser acknowledges that the shares purchased hereby are illiquid, and must be held an indefinite period of time. In addition, the Purchaser has received the Company's business plan and most recent financial statements, and has had an opportunity to discuss the current business and financial condition of the officers of the Company and has received satisfactory responses to all questions asked. The Purchaser understands that the Company's revenues to date have been minimal, and that the Company is not profitable. Moreover, the Company will need additional cash resources in the near future, both to finance its business, and to pay existing indebtedness. The amount of the existing indebtedness currently due and payable or due within the next 90 days, including trade payables and lease payments, is \$500,000. There can be no assurance that additional cash resources will be available at all or on terms satisfactory to the Company. In the event that the Company does not secure additional cash resources, the Company may be required to substantially reduce its operating levels or cease operations altogether. Moreover, if the Company does raise additional cash resources, such financings could result in significant dilution to the Purchaser.

- (d) <u>Investment</u>. The Purchaser is acquiring the Series E Shares and Warrant for investment for the Purchaser's own account, not as a nominee or agent, and not with the view to, or for resale in connection with, any distribution thereof. The Purchaser understands that the Series E Shares and Warrant have not been, and will not be, registered under the Securities Act by reason of a specific exemption therefrom, and that any such exemption would depend, among other things, upon the bona fide nature of the investment intent and the accuracy of such Purchaser's representations as expressed herein. The Purchaser has not been formed for the specific purpose of acquiring the Series E Shares or the Warrant.
- (e) Rule 144. The Purchaser acknowledges that the Series E Shares and the Warrant must be held indefinitely unless subsequently registered under the Securities Act or an exemption from such registration is available. The Purchaser is aware of the provisions of Rule 144 promulgated under the Securities Act which permit limited resale of shares purchased in a private placement subject to the satisfaction of certain conditions, including, among other things, the existence of a public market for the shares, the availability of certain current public information about the Company, the resale occurring not less than two (2) years after a party has purchased and paid for the security to be sold, the sale being effected through a "broker's transaction" or in transactions directly with a "market maker" (as provided by Rule 144(f) and the number of shares being sold during any three (3) month period not exceeding specified limitations.

- (f) No Public Market. The Purchaser understands that no public market now exists for any of the securities issued by the Company, that the Company has made no assurances that a public market will ever exist for the Series E shares and that, even if such a public market exists at some future time, the Company may not then be satisfying the current public information requirements of Rule 144.
- (g) <u>Authorization</u>. This Agreement, when executed and delivered by the Purchaser, will constitute a valid and legally binding obligation of the Purchaser, enforceable in accordance with its terms, subject to laws of general application relating to bankruptcy, insolvency and the relief of debtors and rules of law governing specific performance, injunctive relief or other equitable remedies.

Section 5

Conditions to Closing of Purchaser

The Purchaser's obligation to purchase the Series E Shares at the Closing is, at the option of the Purchaser, subject to the fulfillment or waiver as of the Closing Date of the following conditions:

- 5.1 <u>Representations and Warranties Correct</u>. The representations and warranties made by the Company in Section 3 hereof shall be true and correct in all material respects when made, and shall be true and correct in all material respects on the Closing Date with the same force and effect as if they had been made on and as of said date.
- 5.2 <u>Covenants</u>. All covenants, agreements and conditions contained in this Agreement to be performed by the Company on or prior to the Closing Date shall have been performed or complied with in all respects.
- 5.3 <u>Blue Sky</u>. The Company shall have obtained all necessary Blue Sky law permits and qualifications, or secured exemptions therefrom, required by any state for the offer and sale of the Series E Shares.
- 5.4 <u>Legal Matters</u>. All material matters of a legal nature which pertain to this Agreement and the transactions contemplated hereby shall have been reasonably approved by counsel to the Purchaser, and the Purchaser shall have received an opinion from the Company's counsel, in substantially the form attached hereto as <u>Exhibit D</u>.
- 5.5 <u>Investor Rights Agreement and Voting Agreement</u>. The Company shall have executed and delivered the Investor Rights Agreement in substantially the form of <u>Exhibit E</u> attached hereto, and the Voting Agreement in substantially the form of <u>Exhibit F</u> attached hereto.

Section 6

Conditions to Closing of Company

The Company's obligation to sell and issue the Series E Shares at the Closing is, at the option of the Company, subject to the fulfillment or waiver of the following conditions:

- 6.1 <u>Representations</u>. The representations made by the Purchaser in Section 4 hereof shall be true and correct when made, and shall be true and correct on the Closing Date.
- 6.2 <u>Blue Sky</u>. The Company shall have obtained all necessary Blue Sky law permits and qualifications, or secured exemptions therefrom, required by any state for the offer and sale of the Series E Shares.
- 6.3 <u>Covenants</u>. All covenants, agreements and conditions contained in this Agreement to be performed by the Purchaser on or prior to the Closing Date shall have been performed or complied with in all material respects.
- 6.4 <u>Investor Rights Agreement and Voting Agreement</u>. The Purchaser shall have executed and delivered the Investor Rights Agreement in substantially the form of <u>Exhibit E</u> attached hereto, and the Voting Agreement in substantially the form of <u>Exhibit F</u> attached hereto.

Section 7

Affirmative Covenants of the Company

The Company hereby covenants and agrees as follows:

- 7.1 <u>Financial Information</u>. The Company will mail the following reports to the Purchaser for so long as the Purchaser is a holder of any shares of Series E Shares purchased by such person pursuant to this Agreement:
- (a) As soon as practicable after the end of each fiscal quarter and each fiscal year, audited consolidated balance sheets of the Company and its subsidiaries, if any, as of the end of such fiscal year, and audited consolidated statements of income and consolidated statements of changes in financial position of the Company and its subsidiaries, if any, for such year, prepared in accordance with generally accepted accounting principles.
- (b) For so long as a Purchaser is eligible to receive reports under this Section 7.1, it shall also have the right, at its expense, to visit and inspect any of the properties of the Company or any of its subsidiaries, to examine their books of account and records, and to discuss their affairs, finances and accounts with their

officers, all at such reasonable times and as often as may be reasonably requested; provided however that the Company shall not be obligated to provide any information that it reasonably considers to be a trade secret or to contain confidential information.

- 7.2 Transfer of Information Rights. The information rights set forth in Section 7.1 may be transferred in any non-public transfer of Series E Shares, provided that Company is given written notice of such transfer, and provided further that the right to receive the information set forth in Section 7.1 may only be transferred to a holder of, or affiliated holders who, in the aggregate, hold at least 150,000 Series E Shares, as appropriately adjusted for stock splits and the like. In the event that the Company reasonably determines that provision of information to a transferee pursuant to this Section 7.1 would materially adversely impact its proprietary position, such information may be edited in the manner necessary to avoid such impact.
- 7.3 Termination of Covenants. The covenants set forth in this Section 7 shall terminate on and be of no further force or effect upon the earlier of (i) the consummation of the Company's sale of its Common Stock in an underwritten public offering pursuant to an effective registration statement filed under the Securities Act, immediately subsequent to which the Company shall be obligated to file annual and quarterly reports with the Commission pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934 (the "Exchange Act") or (ii) the registration by the Company of a class of its equity securities under Section 12(b) or 12(g) of the Exchange Act.
- 7.4 <u>Initial Public Offering</u>. The Company will not, without first obtaining the written consent of the Purchaser, issue shares in an initial public offering the gross proceeds of which do not equal or exceed \$15 million.

Section 8

Restrictions on Transferability of Securities: Compliance with Securities Act

- 8.1 Restrictions on Transferability. The Series E Shares and the Warrant and Warrant Shares shall not be sold, assigned, transferred or pledged, except upon the conditions specified in this Section 8, which conditions are intended to ensure compliance with the provisions of the Securities Act. The Purchaser will cause any other proposed purchaser, assignee, transferee, or pledgee of the Series E Shares or the Warrant or Warrant Shares held by the Purchaser to agree to take and hold such securities subject to the provisions and upon the conditions specified in this Section 8.
- 8.2 <u>Restrictive Legend</u>. Each certificate representing (i) the Series E Shares, (ii) any other securities issued in respect of the Series E Shares upon any stock split, stock dividend, recapitalization, merger, consolidation or similar event,

and (iii) the Warrant and the Warrant Shares shall (unless otherwise permitted by the provisions of Section 8.3 below) be stamped or otherwise imprinted with a legend in the following form (in addition to any legend required under applicable state securities laws):

"THE SECURITIES REPRESENTED BY THIS CERTIFICATE HAVE NOT BEEN REGISTERED UNDER THE SECURITIES ACT OF 1933, AS AMENDED (THE 'ACT'), NOR QUALIFIED WITH THE CALIFORNIA COMMISSIONER OF CORPORATIONS. THESE SECURITIES HAVE BEEN ACQUIRED FOR INVESTMENT AND NOT WITH A VIEW TO, OR IN CONNECTION WITH, THE DISTRIBUTION THEREOF. THESE SECURITIES MAY NOT BE OFFERED, SOLD, PLEDGED OR OTHERWISE TRANSFERRED UNLESS (A) A REGISTRATION STATEMENT UNDER THE ACT IS IN EFFECT AS TO THESE SECURITIES, OR (B) THERE IS AN OPINION OF COUNSEL SATISFACTORY TO THE CORPORATION, THAT AN EXEMPTION THEREFROM IS AVAILABLE."

The Purchaser consents to the Company making a notation on its records and giving instructions to any transfer agent of the Series E Shares the Warrant or the Warrant Shares in order to implement the restrictions on transfer established in this Section 8.

8.3 <u>Notice of Proposed Transfers</u>. The holder of each certificate representing securities of the Company required to bear the legend set forth in Section 8.2 ("Restricted Securities"), by acceptance thereof, agrees to comply in all respects with the provisions of this Section 8.3. Prior to any proposed sale, assignment, transfer or pledge of any Restricted Securities, unless there is in effect a registration sale, assignment, transfer or pledge of any Restricted Securities, unless there is in effect a registration statement under the Securities Act covering the proposed transfer, the holder thereof shall give written notice to the Company of such holder's intention to effect such transfer, sale, assignment or pledge. Each such notice shall describe the manner and circumstances of the proposed transfer, sale, assignment or pledge in sufficient detail, and shall be accompanied at such holder's expense by either (i) an unqualified written opinion of legal counsel who shall be, and whose legal opinion shall be, reasonably satisfactory to the Company addressed to the Company, to the effect that the proposed transfer of the Restricted Securities may be effected without registration under the Securities Act, or (ii) a "no action" letter from the Commission to the effect that the transfer of such securities without registration will not result in a recommendation by the staff of the Commission that action be taken with respect thereto, whereupon the holder of such Restricted Securities shall be entitled to transfer such Restricted Securities in accordance with the terms of the notice delivered by the holder to the Company. The Company will not require such a legal opinion or "no action" letter (a) in any transaction in compliance with Rule 144, or (b) in any transaction in which a Purchaser which is a partnership distributes Series E Shares, the Warrant or Warrant Shares solely to partners thereof for no consideration, or transfers by gift, will or intestate succession to the spouse, siblings, lineal descendants or ancestors of any partner, provided that each transferee agrees in writing to be subject to the terms of this Section 8.3. Each

certificate evidencing the Restricted Securities transferred, as above provided, shall bear, except if such transfer is made pursuant to Rule 144, the appropriate restrictive legend set forth in Section 8.2 above, except that such certificate shall not bear such restrictive legend if, in the opinion of counsel for such holder and the Company, such legend is not required in order to establish compliance with any provisions of the Securities Act.

- 8.4 California Corporate Securities Law. THE SALE OF THE SECURITIES WHICH ARE THE SUBJECT OF THIS AGREEMENT HAS NOT BEEN QUALIFIED WITH THE COMMISSIONER OF CORPORATIONS OF THE ISSUING OF SUCH SECURITIES OR THE PAYMENT OR RECEIPT OF ANY PART OF THE CONSIDERATION THEREFOR PRIOR TO SUCH QUALIFICATION IS UNLAWFUL UNLESS THE SALE OF SECURITIES IS EXEMPT FROM THE QUALIFICATION BY SECTION 25100, 25102 OR 25105 OF THE CALIFORNIA CORPORATIONS CODE. THE RIGHTS OF ALL PARTIES TO THIS AGREEMENT ARE EXPRESSLY CONDITIONED UPON SUCH QUALIFICATION BEING OBTAINED, UNLESS THE SALE IS SO EXEMPT.
- 8.5 <u>Market Stand-off</u>. The Purchaser hereunder agrees that in connection with a registered public offering of the Company's securities, if so requested by the Company and the Underwriter's Representative (if any), the Purchaser shall not sell or otherwise transfer any securities of the Company during the 180-day period following the effective date of a registration statement of the Company filed under the Securities Act.

Section 9

Miscellaneous

- 9.1 <u>Governing Law</u>. This Agreement shall be governed by and construed in accordance with the laws of the State of California without giving effect to any choice of law or conflict of law provisions that would cause the application of the laws of any jurisdiction other than that of the State of California.
- 9.2 Finder's Fee. The Company may have entered into, and from time to time may enter into, a finder's fee arrangement with respect to the sale of the Series E Shares. The Company agrees to indemnify and hold harmless the Purchaser from any liability for any commission or compensation in the nature of a finder's fee (and the costs and expenses of defending against such liability or asserted liability) for which the Company or any of its officers, employees or representatives is responsible.
- 9.3 <u>Survival</u>. The representations, warranties, covenants and agreements made herein shall survive any investigation made by the Purchaser and the closing of the transactions contemplated hereby.

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- 9.4 <u>Successors and Assigns</u>. Except as otherwise provided herein, the provisions hereof shall inure to the benefit of, and be binding upon, the successors, assigns, heirs, executors and administrators of the parties hereto; <u>provided</u>, <u>however</u>, that the right of the Purchaser to purchase the Series E Shares shall not be assignable without the prior written consent of the Company.
- 9.5 Entire Agreement; Amendment. This Agreement and the other document delivered pursuant hereto at the Closing constitute the full and entire understanding and agreement between the parties with regard to the subjects hereof and thereof, and supersede all prior agreements, and no party shall be liable or bound to any other party in any manner by any warranties, representations or covenants, except as specifically set forth herein or therein. Except as expressly provided herein, neither this Agreement nor any term hereof may be amended, waived, discharged or terminated other than by a written instrument signed by the party against whom enforcement of any such amendment, waiver, discharge or termination is sought; provided, however, that holders of at least a majority of the Series E Shares purchased hereunder may, with the written consent of the Company, waive, modify or amend on behalf of all holders, any provisions hereof benefiting such holders, so long as the effect thereof will be that all such holders will be treated equally.
- 9.6 Notices, etc. All notices and other communications required or permitted hereunder shall be in writing and shall be mailed by registered or certified mail, postage prepaid, or otherwise delivered by hand or by messenger, addressed (a) if to Purchaser, at such address as the Purchaser shall have furnished to the Company in writing, or (b) if to any other holder of any Series E Shares, at such address as such holder shall have furnished the Company in writing, or until any such holder so furnishes an address to the Company, then to and at the address of the last holder of such Series E Shares who has so furnished an address to the Company, or (c) if to the Company, one copy should be sent to its address set forth on the cover page of this Agreement and addressed to the attention of the President, or at such other address as the Company shall have furnished to the Purchaser.

Each such notice or other communication shall, for all purposes of this Agreement, be treated as effective or having been given when delivered if delivered personally, or, if sent by mail, at the earlier of its receipt or seventy-two (72) hours after the same has been deposited in a regularly maintained receptacle for the deposit of the United States mail, addressed and postage prepaid as aforesaid.

9.7 <u>Delays or Omissions</u>. Except as expressly provided herein, no delay or omission to exercise any right, power or remedy accruing to any holder of any Series E Shares, upon any breach or default of the Company under this Agreement, shall impair any such right, power or remedy of such holder, nor shall it be construed to be a waiver of any such breach or default, or an acquiescence therein, or of or in any similar breach or default thereafter occurring; nor shall any waiver of any single breach or default be deemed a waiver of any other breach or default theretofore or thereafter occurring. Any waiver, permit, consent or approval of any

kind or character on the part of any holder of any breach or default under this Agreement, or any waiver on the part of any holder of any provisions or conditions of this Agreement, must be in writing and shall be effective only to the extent specifically set forth in such writing. All remedies, either under this Agreement or by law or otherwise afforded to any holder, shall be cumulative and not alternative.

- 9.8 <u>Expenses</u>. The Company and the Purchaser shall each bear their own expenses incurred on their behalf with respect to this Agreement and the transactions contemplated hereby.
- 9.9 <u>Counterparts</u>. This Agreement may be executed in any number of counterparts, each of which shall be enforceable against the parties actually executing such counterparts, and all of which together shall constitute one instrument.
- 9.10 Severability. In the event that any provision of this Agreement becomes or is declared by a court of competent jurisdiction to be illegal, unenforceable or void, this Agreement shall continue in full force and effect without said provision; provided that no such severability shall be effective if it materially changes the economic benefit of this Agreement to any party.
- 9.11 <u>Titles and Subtitles</u>. The titles and subtitles used in this Agreement are used for convenience only and are not considered in construing or interpreting this Agreement.

IN WITNESS WHEREOF, the foregoing Agreement is hereby executed as of the date first above written.

"COMPANY"

U.S. MEDICAL INSTRUMENTS, INC. a California corporation

Ву:	 	 ·	
Title:			

"PURCHASER"

THE MEDICINE PARTNERS

Andrew G. Bluhm

Title: Perton

IZIZENIANO IZIZENIANO kind or character on the part of any holder of any breach or default under this Agreement, or any waiver on the part of any holder of any provisions or conditions of this Agreement, must be in writing and shall be effective only to the extent specifically set forth in such writing. All remedies, either under this Agreement or by law or otherwise afforded to any holder, shall be cumulative and not alternative.

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- 9.11 <u>Titles and Subtitles</u>. The titles and subtitles used in this Agreement are used for convenience only and are not considered in construing or interpreting this Agreement.

IN WITNESS WHEREOF, the foregoing Agreement is hereby executed as of the date first above written.

"COMPANY"
U.S. MEDICAL INSTRUMENTS, INC. a California corporation
Ву:
Title:
"PURCHASER"
THE MEDICINE PARTNERS
Ву:
Title:

EXHIBIT A

SCHEDULE OF PURCHASER

Series E Preferred

<u>Purchaser</u>	Number of Shares to be Purchased	Purchase <u>Price</u>	Aggregate <u>Purchase Price</u>
The Bluhm Group	533,334	\$7.50 per share	\$4 million

Series E Warrants

<u>Purchaser</u>	Number of Shares to be Purchased	Purchase <u>Price</u>	Aggregate <u>Purchase Price</u>
The Bluhm Group	106,667	\$7.50 per share	\$800,002

WARRANT TO PURCHASE SHARES OF SERIES E PREFERRED STOCK OF

U.S. MEDICAL INSTRUMENTS, INC.

- 1. Number and Price of Shares Subject to Warrant. Subject to the terms and conditions herein set forth, The Medicine Partners (the "Purchaser") or its assignee(s) in accordance with the terms hereof, is entitled to purchase from U.S. Medical Instruments Inc., a California corporation (the "Company"), at any time until December 19, 1997, One Hundred Six Thousand Six Hundred Sixty Seven (106,667) shares (which number of shares is subject to adjustment as described below) of fully paid and nonassessable shares of Series E Preferred Stock ("Stock") of the Company upon surrender hereof at the principal office of the Company and, at the election of the holder hereof, upon either payment of the purchase price at said office in cash or by check or the cancellation of any present or future indebtedness from the Company to the holder hereof in a dollar amount equal to the purchase price of the Stock for which the consideration is being given. Subject to adjustment as hereinafter provided, the purchase price of one share of Stock (or such securities as may be substituted for one share of Stock pursuant to the provisions hereinafter set forth), referred to herein as the "Warrant Price", is \$7.50.
- 2. Adjustment of Warrant Price and Number of Shares. The number and kind of securities issuable upon the exercise of this Warrant shall be subject to adjustment from time to time upon the happening of certain events as follows:
- (a) Adjustment for Dividends in Stock or Other Securities or Property. In case at any time or from time to time on or after the date hereof the holders of the Stock of the Company (or any shares of stock or other securities at the time receivable upon the exercise of this Warrant) shall have received, or, on or after the record date fixed from the determination of eligible shareholders, shall have become entitled to receive, without payment therefor, other or additional stock or other securities or property (including cash) of the Company by way of dividend, then and in each case, the holder of this Warrant shall, upon the exercise hereof, be entitled to receive, in addition to the number of shares of Stock receivable thereupon, and without payment of any additional consideration therefor, the amount of such other or additional stock or other securities or property (including cash) of the Company which such holder would hold on the date of such exercise had it been the holder of record of such Stock on the date hereof and had thereafter, during the period from the date hereof to and including the date of such exercise, retained such shares and/or all other additional stock available by it as aforesaid during such period, giving effect to all adjustments called for during such period by paragraphs (b) and (c) of this paragraph 2.
- (b) Adjustment for Reclassification, Reorganization or Merger. In case of any reclassification or change of the outstanding securities of the Company

or of any reorganization of the Company (or any other corporation the stock or securities of which are at the time receivable upon the exercise of this Warrant) or any similar corporate reorganization on or after the date hereof, then and in each such case the holder of this Warrant, upon the exercise hereof at any time after the consummation of such reclassification, change, reorganization, merger or conveyance, shall be entitled to receive, in lieu of the Stock or other securities and property receivable upon the exercise hereof prior to such consummation, the stock or other securities or property to which such holder would have been entitled upon such consummation if such holder had exercised this Warrant immediately prior thereto, all subject to further adjustment as provided in paragraphs (a) and (c); and in each such case, the terms of this paragraph 2 shall be applicable to the shares of stock or other securities properly receivable upon the exercise of this Warrant after such consummation.

- (c) Stock Splits and Reverse Stock Splits. If at any time on or after the date hereof the Company shall subdivide its outstanding shares of Stock into a greater number of shares, the Warrant Price in effect immediately prior to such subdivision shall thereby be proportionately reduced and the number of shares receivable upon exercise of the Warrant shall thereby be proportionately increased; and, conversely, if at any time on or after the date hereof the outstanding number of shares of Stock shall be combined into a smaller number of shares, the Warrant Price in effect immediately prior to such combination shall thereby proportionately increased and the number of shares receivable upon exercise of Warrant shall thereby be proportionately decreased.
- (d) Conversion of Series E Preferred Stock. If at any time prior to the expiration of this Warrant, all of the Company's then outstanding Stock is converted into shares of the Company's common stock, then this Warrant shall immediately become exercisable for that number of shares of common stock receivable upon conversion by a holder of the same number of shares of Stock as were subject to this Warrant immediately prior to such conversion, and the Warrant Price shall be immediately adjusted to equal the quotient obtained by dividing (x) the aggregate Warrant Price of the maximum number of shares of Stock for which this Warrant was exercisable immediately prior to such conversion, by (y) the number of shares of common stock for which this Warrant is exercisable immediately after such conversion. After any such conversion, all references herein to Stock shall be deemed to be references to common stock.
- (e) Notice of Adjustment. When any adjustment is required to be made in the number or kind of shares purchasable upon exercise of the Warrant, or in the Warrant Price, the Company shall promptly notify the Purchaser of such event and of the number of shares of Stock or other securities or property thereafter purchasable upon exercise of the Warrant.
- 3. <u>No Fractional Shares</u>. No fractional shares of Stock will be issued in connection with any subscription hereunder. In lieu of any fractional shares which would otherwise be issuable, the Company shall pay cash equal to the product of

such fraction multiplied by the fair market value of one share of Stock on the date of exercise, as determined in good faith by the Company's Board of Directors.

- 4. No Shareholder Rights. This Warrant shall not entitle its holder to any of the rights of a shareholder of the Company.
- 5. Reservation of Stock. The Company covenants that during the period this Warrant is exercisable, the Company will reserve from its authorized and unissued Stock a sufficient number of shares to provide for the issuance of Stock upon the exercise of this Warrant. The Company agrees that its issuance of this Warrant shall constitute full authority to its officers who are charged with the duty of executing stock certificates to execute and issue the necessary certificates for shares of Stock upon the exercise of this Warrant.
- 6. Exercise of Warrant. This Warrant may be exercised by the holder hereof, in whole or in part, by the surrender of this Warrant and the Notice of Exercise attached hereto as Exhibit A duly completed and executed on behalf of the holder hereof, at the principal office of the Company, accompanied by payment in full of the Warrant Price then in effect as described above. This Warrant shall be deemed to have been exercised immediately prior to the close of business on the date of its surrender for exercise as provided above, and the person entitled to receive the shares of Stock issuable upon such exercise shall be treated for all purposes as the holder of such shares of record as of the close of business on such date. As promptly as practicable on or after such date and in any event within ten (10) days thereafter, the Company at its expense shall issue and deliver to the person or persons entitled to receive the same a certificate or certificates for the number of full shares of Stock issuable upon such exercise, together with cash in lieu of any fraction of a share as provided above. The shares of Stock issuable upon exercise hereof shall, upon their issuance, be fully paid and nonassessable. In the event that this Warrant is exercised in part, the Company at its expense will execute and deliver a new Warrant of like tenor exercisable for the number of shares for which this Warrant may then be exercised.
- (a) Net Issue Exercise. Notwithstanding any provisions herein to the contrary, in lieu of exercising this Warrant for cash, the Purchaser may elect to receive shares equal to the value (as determined below) of this Warrant (or the portion thereof being canceled) by surrender of this Warrant at the principal office of the Company together with a properly endorsed notice of exercise and notice of such election in which event the Company shall issue to Purchaser a number of shares of Stock computed using the following formula:

$$X = \frac{Y(A-B)}{A}$$

Where X = the number of shares of Stock to be issued to the Purchaser,

- Y = the number of shares of Stock purchasable under the Warrant or, if only a portion of the Warrant is being exercised, the portion of the Warrant being canceled (at the date of such calculation),
- A = the fair market value of one share of the Company's Stock (at the date of such calculation), and
- B = the Warrant Price (as adjusted to the date of such calculation).

For purposes of the above calculation, fair market value of one share of Stock shall be determined by the Company's Board of Directors in good faith; provided, however, that where there exists a public market for the Stock at the time of such exercise, fair market value shall mean the average over the preceding twenty (20) trading days (or such fewer number of days as such public market has existed) of the mean of the high closing bid and asked prices on the over-the-counter market as reported by Nasdaq, or if then traded on a national securities exchange or the Nasdaq National Market, the average over the preceding twenty (20) trading days (or such fewer number of days as the Stock has been so traded) of the mean of the high and low prices on the principal national securities exchange or the National Market on which it is so traded.

- 7. <u>Term of Warrant</u>. This Warrant expires and shall no longer be exercisable as of 11:59 p.m. Pacific standard time, December 15, 1997, and shall be void thereafter.
- 8. <u>Certificate of Adjustment</u>. Whenever the Warrant Price or number or type of securities issuable upon exercise of this Warrant is adjusted, as herein provided, the Company shall promptly deliver to the record holder of this Warrant a certificate of an officer of the Company setting forth the nature of such adjustment and a brief statement of the facts requiring such adjustment.
- 9. <u>Transfer of Warrant</u>. This Warrant may be freely transferred or assigned by the Purchaser in whole or in part, subject to compliance with all federal and state securities laws by the transferor and the transferee.
- 10. Replacement of Warrants. On receipt of evidence reasonably satisfactory to the Company of the loss, theft, destruction or mutilation of any Warrant and, in the case of any such loss, theft or destruction of any Warrant, on delivery of an indemnity agreement or security reasonably satisfactory in form and amount to the Company or, in the case of any such mutilation, on surrender and cancellation of such Warrant, the Company at its expense will execute and deliver, in lieu thereof, a new Warrant of like tenor.
- 11. <u>Miscellaneous</u>. This Warrant shall be governed by the laws of the State of California. The headings in this Warrant are for purposes of convenience and reference only, and shall not be deemed to constitute a part hereof. Neither this Warrant nor any term hereof may be changed, waived, discharged or terminated

orally but only be an instrument in writing signed by the Company and the registered holder hereof. All notices and other communications from the Company to the holder of this Warrant shall be mailed by first class registered or certified mail, postage prepaid, to the address furnished to the Company in writing by the last holder of this Warrant who shall have furnished an address to the Company in writing. The invalidity or unenforceability of any provision hereof shall in no way affect the validity or enforceability of any other provisions.

12. <u>Termination</u> This Warrant (and the right to purchase securities upon exercise hereof) shall terminate on December 19, 1997.

ISSUED this 19th day of December, 1994

U.S. N	MEDICAL INSTRUMENTS, INC.	
Ву:	Matthew S. Mazur, President	_

EXHIBIT A

NOTICE OF INTENT TO EXERCISE (To be signed only upon exercise of Warrant)

To: U.S. MEDICAL INSTRUMENTS, INC.

	f the within Warrant, hereby irrevocably
elects to exercise the purchase right represen thereunder,	
thereunder,U.S. Medical Instruments, Inc. and herewith	makes payment of
(\$) thereof, as shares be issued in the name off, and deliver , whose address is	red to
The undersigned represents that account for investment and not with a view distribution thereof (subject, however, to any thereof shall at all times be within its control	requirement of law that the disposition
DATED:	
	BLUHM GROUP
	Ву:
Address:	

WARRANT TO PURCHASE SHARES OF SERIES E PREFERRED STOCK OF

U.S. MEDICAL INSTRUMENTS, INC.

- 1. Number and Price of Shares Subject to Warrant. Subject to the terms and conditions herein set forth, The Medicine Partners (the "Purchaser") or its assignee(s) in accordance with the terms hereof, is entitled to purchase from U.S. Medical Instruments Inc., a California corporation (the "Company"), at any time until December 19, 1997, One Hundred Six Thousand Six Hundred Sixty Seven (106,667) shares (which number of shares is subject to adjustment as described below) of fully paid and nonassessable shares of Series E Preferred Stock ("Stock") of the Company upon surrender hereof at the principal office of the Company and, at the election of the holder hereof, upon either payment of the purchase price at said office in cash or by check or the cancellation of any present or future indebtedness from the Company to the holder hereof in a dollar amount equal to the purchase price of the Stock for which the consideration is being given. Subject to adjustment as hereinafter provided, the purchase price of one share of Stock (or such securities as may be substituted for one share of Stock pursuant to the provisions hereinafter set forth), referred to herein as the "Warrant Price", is \$7.50.
- 2. Adjustment of Warrant Price and Number of Shares. The number and kind of securities issuable upon the exercise of this Warrant shall be subject to adjustment from time to time upon the happening of certain events as follows:
- (a) Adjustment for Dividends in Stock or Other Securities or Property. In case at any time or from time to time on or after the date hereof the holders of the Stock of the Company (or any shares of stock or other securities at the time receivable upon the exercise of this Warrant) shall have received, or, on or after the record date fixed from the determination of eligible shareholders, shall have become entitled to receive, without payment therefor, other or additional stock or other securities or property (including cash) of the Company by way of dividend, then and in each case, the holder of this Warrant shall, upon the exercise hereof, be entitled to receive, in addition to the number of shares of Stock receivable thereupon, and without payment of any additional consideration therefor, the amount of such other or additional stock or other securities or property (including cash) of the Company which such holder would hold on the date of such exercise had it been the holder of record of such Stock on the date hereof and had thereafter, during the period from the date hereof to and including the date of such exercise, retained such shares and/or all other additional stock available by it as aforesaid during such period, giving effect to all adjustments called for during such period by paragraphs (b) and (c) of this paragraph 2.
- (b) Adjustment for Reclassification, Reorganization or Merger. In case of any reclassification or change of the outstanding securities of the Company

or of any reorganization of the Company (or any other corporation the stock or securities of which are at the time receivable upon the exercise of this Warrant) or any similar corporate reorganization on or after the date hereof, then and in each such case the holder of this Warrant, upon the exercise hereof at any time after the consummation of such reclassification, change, reorganization, merger or conveyance, shall be entitled to receive, in lieu of the Stock or other securities and property receivable upon the exercise hereof prior to such consummation, the stock or other securities or property to which such holder would have been entitled upon such consummation if such holder had exercised this Warrant immediately prior thereto, all subject to further adjustment as provided in paragraphs (a) and (c); and in each such case, the terms of this paragraph 2 shall be applicable to the shares of stock or other securities properly receivable upon the exercise of this Warrant after such consummation.

- (c) Stock Splits and Reverse Stock Splits. If at any time on or after the date hereof the Company shall subdivide its outstanding shares of Stock into a greater number of shares, the Warrant Price in effect immediately prior to such subdivision shall thereby be proportionately reduced and the number of shares receivable upon exercise of the Warrant shall thereby be proportionately increased; and, conversely, if at any time on or after the date hereof the outstanding number of shares of Stock shall be combined into a smaller number of shares, the Warrant Price in effect immediately prior to such combination shall thereby proportionately increased and the number of shares receivable upon exercise of Warrant shall thereby be proportionately decreased.
- (d) Conversion of Series E Preferred Stock. If at any time prior to the expiration of this Warrant, all of the Company's then outstanding Stock is converted into shares of the Company's common stock, then this Warrant shall immediately become exercisable for that number of shares of common stock receivable upon conversion by a holder of the same number of shares of Stock as were subject to this Warrant immediately prior to such conversion, and the Warrant Price shall be immediately adjusted to equal the quotient obtained by dividing (x) the aggregate Warrant Price of the maximum number of shares of Stock for which this Warrant was exercisable immediately prior to such conversion, by (y) the number of shares of common stock for which this Warrant is exercisable immediately after such conversion. After any such conversion, all references herein to Stock shall be deemed to be references to common stock.
- (e) Notice of Adjustment. When any adjustment is required to be made in the number or kind of shares purchasable upon exercise of the Warrant, or in the Warrant Price, the Company shall promptly notify the Purchaser of such event and of the number of shares of Stock or other securities or property thereafter purchasable upon exercise of the Warrant.
- 3. <u>No Fractional Shares</u>. No fractional shares of Stock will be issued in connection with any subscription hereunder. In lieu of any fractional shares which would otherwise be issuable, the Company shall pay cash equal to the product of

such fraction multiplied by the fair market value of one share of Stock on the date of exercise, as determined in good faith by the Company's Board of Directors.

- 4. No Shareholder Rights. This Warrant shall not entitle its holder to any of the rights of a shareholder of the Company.
- 5. Reservation of Stock. The Company covenants that during the period this Warrant is exercisable, the Company will reserve from its authorized and unissued Stock a sufficient number of shares to provide for the issuance of Stock upon the exercise of this Warrant. The Company agrees that its issuance of this Warrant shall constitute full authority to its officers who are charged with the duty of executing stock certificates to execute and issue the necessary certificates for shares of Stock upon the exercise of this Warrant.
- 6. Exercise of Warrant. This Warrant may be exercised by the holder hereof, in whole or in part, by the surrender of this Warrant and the Notice of Exercise attached hereto as Exhibit A duly completed and executed on behalf of the holder hereof, at the principal office of the Company, accompanied by payment in full of the Warrant Price then in effect as described above. This Warrant shall be deemed to have been exercised immediately prior to the close of business on the date of its surrender for exercise as provided above, and the person entitled to receive the shares of Stock issuable upon such exercise shall be treated for all purposes as the holder of such shares of record as of the close of business on such date. As promptly as practicable on or after such date and in any event within ten (10) days thereafter, the Company at its expense shall issue and deliver to the person or persons entitled to receive the same a certificate or certificates for the number of full shares of Stock issuable upon such exercise, together with cash in lieu of any fraction of a share as provided above. The shares of Stock issuable upon exercise hereof shall, upon their issuance, be fully paid and nonassessable. In the event that this Warrant is exercised in part, the Company at its expense will execute and deliver a new Warrant of like tenor exercisable for the number of shares for which this Warrant may then be exercised.
- (a) Net Issue Exercise. Notwithstanding any provisions herein to the contrary, in lieu of exercising this Warrant for cash, the Purchaser may elect to receive shares equal to the value (as determined below) of this Warrant (or the portion thereof being canceled) by surrender of this Warrant at the principal office of the Company together with a properly endorsed notice of exercise and notice of such election in which event the Company shall issue to Purchaser a number of shares of Stock computed using the following formula:

$$\chi = \frac{Y(A-B)}{A}$$

Where X = the number of shares of Stock to be issued to the Purchaser,

- Y = the number of shares of Stock purchasable under the Warrant or, if only a portion of the Warrant is being exercised, the portion of the Warrant being canceled (at the date of such calculation),
- A = the fair market value of one share of the Company's Stock (at the date of such calculation), and
- B = the Warrant Price (as adjusted to the date of such calculation).

For purposes of the above calculation, fair market value of one share of Stock shall be determined by the Company's Board of Directors in good faith; provided, however, that where there exists a public market for the Stock at the time of such exercise, fair market value shall mean the average over the preceding twenty (20) trading days (or such fewer number of days as such public market has existed) of the mean of the high closing bid and asked prices on the over-the-counter market as reported by Nasdaq, or if then traded on a national securities exchange or the Nasdaq National Market, the average over the preceding twenty (20) trading days (or such fewer number of days as the Stock has been so traded) of the mean of the high and low prices on the principal national securities exchange or the National Market on which it is so traded.

- 7. <u>Term of Warrant</u>. This Warrant expires and shall no longer be exercisable as of 11:59 p.m. Pacific standard time, December 15, 1997, and shall be void thereafter.
- 8. <u>Certificate of Adjustment</u>. Whenever the Warrant Price or number or type of securities issuable upon exercise of this Warrant is adjusted, as herein provided, the Company shall promptly deliver to the record holder of this Warrant a certificate of an officer of the Company setting forth the nature of such adjustment and a brief statement of the facts requiring such adjustment.
- 9. <u>Transfer of Warrant</u>. This Warrant may be freely transferred or assigned by the Purchaser in whole or in part, subject to compliance with all federal and state securities laws by the transferor and the transferee.
- 10. Replacement of Warrants. On receipt of evidence reasonably satisfactory to the Company of the loss, theft, destruction or mutilation of any Warrant and, in the case of any such loss, theft or destruction of any Warrant, on delivery of an indemnity agreement or security reasonably satisfactory in form and amount to the Company or, in the case of any such mutilation, on surrender and cancellation of such Warrant, the Company at its expense will execute and deliver, in lieu thereof, a new Warrant of like tenor.
- 11. <u>Miscellaneous</u>. This Warrant shall be governed by the laws of the State of California. The headings in this Warrant are for purposes of convenience and reference only, and shall not be deemed to constitute a part hereof. Neither this Warrant nor any term hereof may be changed, waived, discharged or terminated

orally but only be an instrument in writing signed by the Company and the registered holder hereof. All notices and other communications from the Company to the holder of this Warrant shall be mailed by first class registered or certified mail, postage prepaid, to the address furnished to the Company in writing by the last holder of this Warrant who shall have furnished an address to the Company in writing. The invalidity or unenforceability of any provision hereof shall in no way affect the validity or enforceability of any other provisions.

12. <u>Termination</u>. This Warrant (and the right to purchase securities upon exercise hereof) shall terminate on December 19, 1997.

ISSUED this 19th day of December, 1994

U.S.	MEDICAL INSTRUMENTS, INC.
_	
Ву:	Matthew S. Mazur, President

EXHIBIT A

NOTICE OF INTENT TO EXERCISE (To be signed only upon exercise of Warrant)

To: U.S. MEDICAL INSTRUMENTS, INC.

elects to exercise the purchase right represen	
thereunder,	makes payment of
(\$) thereof, a	nd requests that the certificates for such
shares be issued in the name off, and delivery whose address is	
The undersigned represents the account for investment and not with a view distribution thereof (subject, however, to any thereof shall at all times be within its contro	requirement of law that the disposition
DATED:	
	BLUHM GROUP
	Ву:
Address:	

orally but only be an instrument in writing signed by the Company and the registered holder hereof. All notices and other communications from the Company to the holder of this Warrant shall be mailed by first class registered or certified mail, postage prepaid, to the address furnished to the Company in writing by the last holder of this Warrant who shall have furnished an address to the Company in writing. The invalidity or unenforceability of any provision hereof shall in no way affect the validity or enforceability of any other provisions.

12. <u>Termination</u>. This Warrant (and the right to purchase securities upon exercise hereof) shall terminate on December 19, 1997.

ISSUED this 19th day of December, 1994

U.S. MEDICAL INSTRUMENTS, INC.

Bv:

Matthew S. Mazur, President

CROSS RECEIPT

U.S. Medical Instruments, Inc. (the "Company") hereby acknowledges the receipt of \$4,000,000 from The Medical Partners (the "Purchaser") as payment in full for 533,334 shares of Series E Preferred Stock of the Company.

Dated: As of December 19, 1994

U.S. Medial Instruments, Inc.

Title: President and Chief

Executive Officer

Purchaser hereby acknowledges receipt from the Company of certificate number PE-176 representing 533,334 shares of the Company's Series E Preferred Stock.

Dated:

As of December 19, 1994

The Medical Partners

Title:

GT\5501994

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    Attorneys for BRIAN GREENSPUN and
13
    G.C. INVESTMENTS
14
15
                        UNITED STATES DISTRICT COURT
16
                       SOUTHERN DISTRICT OF CALIFORNIA
17
18
    THE MEDICINE PARTNERS, an
                                         Case No. 96-1187-H (CGA)
    Illinois PARTNERSHIP; G.C.
19
    INVESTMENTS, LLC, a Nevada
                                         DECLARATION OF SERVICE
    Limited Liability Corporation,
20
                Plaintiffs,
21
    v.
22
    U.S. MEDICAL INSTRUMENTS, INC.,
    a California Corporation;
23
    MATTHEW S. MAZUR, a California
    citizen,
24
25
                Defendants.
26
27
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I am employed in the City of San Diego, County of San Diego,
State of California. I am over the age of 18 years and not a party

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to the within action. My business address is 550 West "C" Street, 19th Floor, San Diego, California 92101.

On October 28, 1996, I caused to be personally served, the document(s) named below on the parties in this action as follows:

1. FIRST AMENDED COMPLAINT FOR DAMAGES OR RESCISSION;

MATERIAL MISREPRESENTATIONS; AND/OR OMISSIONS IN THE SALE

OF STOCK; JURY DEMAND

SERVED UPON:

Nathan Arrington, Esq.
MAZZARELLA, DUNWOODY, WILSON & PETTY
550 West "C" Street, Suite 1050
San Diego, California 92101-3532
(619) 236-9600
Attorneys for Defendants

I declare under penalty of perjury under the laws of the State of California and the United States of America that the foregoing is true and correct.

Executed this 28th day of October 1996, at San Diego, California.

Amy Mertens

eletena